Federal Democratic Republic of Ethiopia Environmental and Social Management Framework (ESMF)

For

Africa CDC Regional Investment Financing Program (ACRIFP)

(Revised ESMF Report)

Addis Ababa, May 2019

List of Abbreviations

ACRIFP	Africa CDC Regional Investment Financing Program
AMR	Antimicrobial Resistance
BSL	Bio-safety Level
CDC	Centre for Diseases Prevention and Control
EA	Environmental Assessment
EIA	Environmental Impact Assessment
EMP	Environmental Management Plan
EOC	Emergency Operating Centre
EPHI	Ethiopian Public Health Institute
EPLAUA	Environmental Protection, Land Administration and Use Authority
ESIA	Environmental and Social Impact Assessment
ESMP	Environmental and Social Management Plan
FDRE	Federal Democratic Republic of Ethiopia
FEPA	Federal Environmental Protection Authority
FEPA	Federal Environmental Protection Authority
FEPA	Federal Environmental Protection Agency
FECCC	Forest Environmental and Climate Change Commission
FMOH	Federal Ministry of Health
GF	Global Fund
GoE	Government of Ethiopia
GTP	Growth and Transformation Plan
HCF	Health Care Facility
HCW	Health Care Waste
HCWM	Health Care Waste Management
HCWMNG	Healthcare Waste Management National Guideline
HCWMP	Health Care Waste Management Plan
HIV	Human Immunodeficiency Virus
HSDP	Health Sector Development Plan
HWMNG	Healthcare Waste Management National Guideline
HWMP	Health Waste Management Plan
IPPS	Infection Prevention and Patient Safety
MDG	Millennium Development Goals

MOH	Ministry of Health
MPA	Multiphase Programmatic Approach
OP	Operational Policy
RG	Risk group
PHEM	Public Health Emergency Management Unit (PHEM)
PHID	Public health infrastructure directorate
PPSD	Project Procurement Strategy for Development
PVC	Polyvinylchloride
RHB	Regional Health Bureau
SNNPRS	Southern Nations, Nationalities, and People's Regional State
TB	Tuberculosis
WHO	World Health Organization

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Executive Summary

Project Background

The Strategic Plan Management of Ethiopian Public Health Institute (EPHI) (2015/16 to 2019/20) together with the Ethiopian Action Plan for Health Security (2018-2022) is enthused and determined for the construction and furnishing of high-level Biosafety Level (BSL-2) laboratory complex in 15 BSL 2 regional laboratories and equipping of 8 BSL 2 regional laboratories constructed by Global Fund. The Africa CDC Regional Investment Financing Program (ACRIFP) project is part of this initiative. World Bank is supporting the East Africa Public Health Laboratory Networking Project by providing finance for the implementation of the start-up phase of (ACRIFP) in Ethiopia. This will involve supporting the set-up of the institutional framework and delivery systems and launching the constructions of BSL 3 laboratory at EPHI ,15 Regional reference laboratories and equipping and furnishing 8 district laboratories constructed by Global fund in Tigray, Afar, Amhara, Oromia, Somali, SNNPRS, Benishangul Gumuz and Gambella regional states and Addis Ababa city administration.

Project description

The proposed project will support vital institutional capacity-building efforts by the Africa CDC headquarters in Addis Ababa, the SA-RCC in Lusaka, and the Ethiopian and Zambian health authorities**.** To be specific project, component that encompasses the Ethiopian project is that the regional capacities/activities to be financed by the project, include, inter alia: (i) the design, construction, equipping and furnishing and maintenance of a Biosafety Level 3 (BSL-3) national reference laboratory (NRL) including a laboratory medical equipment maintenance centre (LEMC); (ii) establishment of a Proficiency Testing System and panel production (PTPC), biobank centre, central warehouse; (iii) construction, equipping and furnishing of 15 laboratories along Ethiopia's borders; (iv) equipping and furnishing 8 Biosafety Level 2 (BSL-2) district laboratories already constructed by the Global Fund; and (v) a set of programs designed to improve laboratory capacity building and operational effectiveness.

Legal, policy and administration framework

Environmental management of the ACRIFP will be evaluated based on the existing environmental and social management systems of Ethiopia and the safeguard policies of the World Bank (WB).

National Proclamations and guidelines pertinent to the project

The following are list of the national environmental policies relevant to the project.

- Environmental Proclamation 299/2002, Environmental Impact Assessment
- Proclamation 513/2007, Solid Waste Management
- Proclamation 300/2002, Environmental Pollution Control
- ESIA Directive 1/ 2008, Directive to Determine Projects Subject to Environmental Impact
- ESIA Guideline, July 2000
- Waste Handling and Disposal Guideline, 1997
- The Guideline for Waste Handling and Disposal in Health Facilities (2006)
- Ethiopian Water Resources Management Proclamation, No. 197/2000

World Bank safeguards Policies

The World Bank Safeguard policies provide guidelines aimed at preventing and mitigating undue harm to people and to the environment, when implementing development projects. As result the World Bank requires environmental assessment (EA) of projects proposed for Bank financing to help ensure that they are environmentally sound and sustainable, and thus to improve decision making. Environmental Assessment is one of the 10 environmental and social Safeguard Policies that WBG uses to examine potential environmental risks and benefits associated with Bank lending operations.

These policies provide a platform for the participation of stakeholders in project design and implementation. During project preparation, the World Bank examines the implications of the proposed project against the following safeguard policies:

- Environmental Assessment (OP/BP 4.01)
- Natural Habitats (OP/BP 4.04)
- Pest Management (OP/BP 4.09)
- Physical Cultural Resources (OP/BP 4.11)
- Involuntary Resettlement (OP/BP 4.12)
- International Waterways (OP/BP 7.50),
- Projects in disputed areas (OP/BP 7.60),
- Forests (OP 4.36) and Safety of Dams (OP 4.37)

The Proposed project triggered Environmental Assessment (OP/BP 4.01) & Physical Cultural Resources (OP/BP 4.11) of the World Bank Safe Guard Policies. The Bank's policy on Involuntary Resettlement (OP/BP 4.12) has not been triggered as the BSL2 labs will be constructed within the premises of government owned health facilities/ hospitals. As a result, the project is not expected to cause any involuntary resettlement or loss asset.

Objectives of the Environmental social management framework (ESMF)

The objective of preparing of the ESMF is to minimize the adverse environmental and social impacts resulting from the implementation of ACRIFP sub project of the construction of 15 BSL 2 laboratories and other 8 BSL 2 laboratories, to be furnished and equipped that being constructed by Global Fund (GF), by incorporating appropriately mitigation measures.

Study Methodology

The following methodology was used in collection data/in useful in the preparation of ESMF.

- **Literature Review:** Review of relevant documents and national policies, laws, regulations pertinent to the project and the World Bank Safeguard policies that is triggered by the ACRIFP.
- **Consultation with stakeholders:** Consultation with major project stakeholders, communities and government officials from Regional States has been conducted to discuss on the ways and means of enhancing the positive impacts and minimize the adverse effect from the this project. List of participants' consultations is annexed to this document.
- **Field observation:** Physical observation on the project sites that will be influenced by the project has been made

Positive impacts

ACRIFP will have potential socio-economic and environmental benefits. The possible positive impacts of the project include enhanced capacity at different levels, job creation, household income improvement, human health, improvement of Health in Ethiopia, centre of excellence, Strengthen national public health surveillance system, Improve detection capacity of antimicrobial resistant microbes: Contribute to Global and Regional Health Objectives, Enhance diagnostic service for vulnerable groups and provide access to routine laboratory diagnostic services etc.

Negative Impacts

The following negative impacts are expected to result during planning, construction and decommissioning phases of the proposed project.

Pre-construction phase

Impact due to Faulty Planning and design - During design phase, the layout of the proposed laboratories may not meet the standard of the laboratories facilities infrastructure requirements and due to this the laboratory personnel may be exposed to infectious diseases and occupational health hazards. To minimize this impact due to faulty design, WBG EHS Guidelines and WHO Laboratory Bio-safety Manual elaborated in detail in the impact chapter is recommended to be followed.

Construction phase

Impact on the laboratory staff and on patients-Construction activities would create risks to patients and staff and may also adversely impact on the existing laboratory diagnosis affecting the day to day operation of the hospital. Access to the construction site would be restricted and Hazardous conditions would be removed from construction sites to minimize impacts.

Impact on soil- excavation of soil and movement of heavy vehicles and equipment is expected to aggravate soil erosion. Light construction machinery would be used and excavation would be strictly carried out within the space provided in the layout and rescheduling to carry out construction during the dry season to minimize impact.

Impact on Vegetation-Some vegetation within the existing hospitals may need to be cleared to construct the new laboratory. Limit extent of trees and vegetation removal and planting trees to compensate losses would minimize impact.

Impact on Landscape-Piles of construction wastes and packaging materials may affect the scenery of the hospital and also restrict peoples' movement within the premises of the hospital. The construction wastes and packaging materials would be regularly collected, transported and properly disposed on a site designated for this purpose to minimize impacts.

Impacts on Water resources- Nearby rivers, streams and springs may be polluted and silt may be deposited in the river courses due to the construction wastes, on-site makeshift toilets, fuel and lubricant from garages and construction machineries and sediments that may be generated due to movement of vehicles. To minimize these impacts, construction wastes would be

regularly collected and disposed and lubricant and oil released from garages and construction machineries would be contained and properly disposed on a site designated for this purpose.

Impact on Air Quality-Construction activities may generate emission of fugitive dust caused by a combination of on-site excavation and movement of earth materials, contact of construction machinery with bare soil, and exposure of bare soil and soil piles to wind. To minimize air pollution from earthmoving machineries water would be sprayed on access roads and construction sites and loose soil would be compacted and construction machinery would be regularly maintained.

Impact due to Noise, vibration and Dust-During construction, noise and vibration may be caused by the operation of pile drivers, earth moving and excavation equipment, concrete mixers, cranes and the transportation of equipment, materials and people. This would create occupational health risks to the patients, construction workers and communities. Planning activities in consultation with local communities so that activities with the greatest potential to generate noise are planned during periods of the day that would result in least disturbance and construction activities during night time would be avoided to minimize impacts.

Traffic accident due to moving machinery- -Material haulage trucks as well as pedestrians around the construction sites may create traffic congestion and may increase of traffic accident. Planning and segregating the location of vehicle traffic, machine operation, and walking areas, and controlling vehicle traffic through the use of one-way traffic routes, establishment of speed limits, and on-site trained flag people wearing high-visibility vests would minimize impacts

Intensification of Malaria-Increased incidence of communicable and vector-borne diseases attributable to construction activities represents a potentially serious health threat to project personnel and residents of local communities.-Prevention of larval and adult propagation through sanitary improvements and elimination of breeding habitats close to human settlements would minimize impact.

Impact due to propagation of infectious diseases-Impacts associate with interaction of workers (contractors) with the community may lead to the propagation of infectious diseases. Undertaking health awareness and education initiatives, for example, by implementing an information strategy to reinforce person-to-person counselling addressing systemic factors that can influence individual behaviour as well as promoting individual protection, and protecting others from infection, by encouraging condom use

Impact on the existing facilities -Water pipes, telephone and electric cables may be interrupted due to construction. The contractor would relocate water pipes, telephone and electric cables from the construction site and contingency plan would be prepared to provide water and power to the community during interruption of power and water supply to the community to minimize impact.

Operation phase
Risks associated with operation of BSL 2 laboratory

Bio-safety Level 2 is expected to handle human-derived blood, body fluids, tissues, or primary human cell lines where the presence of an infectious agent may be unknown. In addition there is risk during specimen handling, processing and transportation due to accidental leakage or spillage from specimens. If appropriate work processes, engineering, and administrative controls are not in place to avoid release of biological agents into the environment, and practices that can have serious impact on the community. As mitigation measures, the facility, containment devices, administrative controls, and procedures that constitute BSL-2 would be designed to maximize safe working conditions for laboratory personnel working with infectious agents. Personnel working in BSL 2 must receive specific training in handling infectious agents and associated procedures and follow the WHO laboratory safety manual and CDC recommends a strategies to minimize risks associated to BSL 2 laboratories. For instance, persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory, eating, drinking, smoking, and storing food must not be permitted in laboratory areas, mouth pipetting is prohibited; laboratory equipment would be routinely decontaminated, spills involving infectious materials must be contained, decontaminated, and cleaned up by trained staff.

Impact of Improper management of waste

During the operational phase of the BSL 2 laboratories, it is anticipated that solid and liquid wastes are generated as non-hazards and infectious/hazardous waste. Therefore, improper and inadequate waste handling, decontamination and disposal can cause public health risks. To avoid the improper management of waste, waste management system would be established and implemented and all personnel working in laboratory would be trained on the waste handling, treatment and disposal. The mitigation measures would include the following strategies:

BSL 2 laboratories waste management

The operation of BSL 2 laboratory generates both non-hazardous and hazardous wastes and the hazardous wastes expected from the laboratories would be infectious liquid and solid waste, pathological wastes, microbiological wastes, sharps, chemical and disposable wastes. So it is important to design a waste management strategy that enables to handle hazardous wastes aseptically to protect staff, community and environment. Thus, mitigation strategies stipulated to manage wastes generated from the BSL 2 facility encompasses waste minimization, segregation, packaging, colour coding, collection, handling, storage, transportation, treatment and disposal.

Waste Minimization: The best practice is to ensure that each laboratory section minimizes their waste generation (all classes of wastes) to the barest possible minimum.

Segregation: Proper segregation of waste at source generation is essential, efficient and effective in managing HCW. Wastes from the BSL 2 would be segregated in accordance with WHO's recommendation, into separate and appropriate temporary storage color-coded containers/bags.

Packaging: The waste packaging would be implemented from its point of origin to the point at which it is treated and disposed and the packaging would be based on the type of wastes generated and the management includes: sharps would be placed in rigid, puncture-resistant containers made of glass, rigid plastic, or cardboard. Solid wastes would be placed in tear-resistant plastic bags. Liquid infectious wastes would be placed in capped bottles or flasks; large quantities would be placed in containment tanks.

Colour Coding: Colour coding is one of the efficient ways of achieving segregation of waste and it helps to minimize and avoid mixing different wastes. The color-coding system would be as follow: Black for non-hazardous waste, yellow for infectious waste, including safety boxes. Red for heavy metal or effluent. White for vials or glass bottles for recycling or reuse.

Waste Collection and Handling: waste would be collected in containers/bags and sealed when filled 3/4 full and all HCW would be sorted on site before collection and transportation using closed wheeled trolleys. All Infectious waste including pathological waste would be collected using yellow bag with biohazard symbol;, and all wastes would be placed leak-proof strong plastic bag or a container (capable of being autoclaved). Sharps waste would be collected with yellow puncture-proof container with biohazard symbol and and would never be emptied or opened. Chemical waste would be collected using brown bags, and labelled with appropriate hazard symbol. Non-hazardous waste would be collected using black bags/ inside a container or container which is disinfected after use. All personnel handling infectious/hazardous waste would obligated to wear personnel protective equipment (PPE) as require. All waste containers would be labelled with type of waste; name of the department, date of collection and, warning of hazardous nature.

Waste Storage

BSL 2 laboratory would designate an area within its premises where waste can be temporarily stored until final collection for disposal and treatment. It is expected that BSL 2 laboratory would manage the HCW it generates as follow: Infectious & Pathological waste storage, the storage place would be identified as an infectious waste area by using the biohazard sign, and floors and walls would be sealed or tiled to allow easy disinfection. Chemical waste storage, when planning storage places for hazardous chemical waste, the characteristics of the different chemicals to be stored and disposed of would be considered (inflammable, corrosive, explosive). The storage place would be an enclosed area and separated from other waste storage areas.

Transportation

Waste transportation involves conveying of wastes from the various points of generation within a laboratory to a temporary storage location and to treatment (incinerator) and disposal facility. All waste bags/containers would be intact and covered with lids and it would be transported using carts, or containers. Infectious waste can be transported together with used sharps waste using intact and leak-proof strong plastic bag or a container. Infectious waste would not be transported together with other hazardous and non-hazardous waste. Chemical waste would be transported separately in boxes to storage sites, and transport staff would always wear appropriate PPE.

Waste treatment and disposal

The hazardous wastes generated during laboratory operation would be managed on site of collection or generated using the methods of steam sterilization, incineration, thermal inactivation, gas/vapor sterilization, chemical disinfection, and sterilization by radiation in accordance with the HCWM guideline and best practices, World Health Organization (WHO) biosafety laboratory manual, WHO safe management of wastes from Healthcare Guideline and World Bank Groups guideline on Environmental health and safety guideline (WBG EHS).

Non-Hazardous Waste: This waste would be disposed of similarly to domestic in municipal waste collection. The liquid waste, though would undergo a treatment in a septic tank packed with different level of gravels and coarse materials.

Highly Infectious Wastes (Items contaminated with blood and body fluids, including cotton, pathological wastes, culture wastes and other infectious wastes)**:** These wastes would be autoclaved at a temperature of 121°C for at least 20 minutes at source. Or it would be treated in a concentrated solution of Sodium Hypochlorite (NaClO) before being disposed with other wastes.

Liquid Waste (infectious & chemical wastes): Collected body fluids, blood and other infectious liquids would be treated using 5% sodium hypochlorite (NaOCl –bleach) and drained into septic tank as well as liquid chemical waste would be diluted/neutralized and disposed to the sewer with water.

Sharps (Needles, syringes, blades, glass, etc.) This waste would be incinerated before being landfilled. In the alternative, they would be encapsulated and then landfilled.

Finally, all wastes would be incinerated using the two chambers/pyrolytic technology incinerator that is primarily designed for the pyrolysis of healthcare and chemical hazardous waste management. For those do not have this incinerator, the two chambers/pyrolytic technology incinerator would be constructed as part of the project in order to prevent environmental pollution. After incinerating the waste, the final ash waste would be disposed in an ash pit designed for disposal

Impact of Hazardous Laboratory Chemicals and Other Agents

Exposure or accidentally spilled hazardous laboratory chemicals would adversely affect human health and the environment if they are not properly managed. To mitigate these hazards, all staff would have training in controlling of chemical hazardous and handling. Only amounts of chemicals necessary for daily use would be stored in the laboratory. Implementing engineering and administrative control measures to avoid the release of hazardous substances into the work environment. Appropriately first-aid stations would be easily accessible throughout the place of work, with Materials Safety Data Sheets (MSDS).

Occupational health and safety risks: during operation of the BSL 2 laboratory may affect Occupational Health and Safety-Health and safety of healthcare providers, cleaning and other supporting staff personnel, and workers involved in waste management handling. To avoid this risk, following OSHA for Laboratory Safety Guidance standards and WHO Laboratory bio-safety

manual recommendation all staff would be trained on safe work practices and guidelines and ensure that they adhere to them and on how to prevent and manage incidences, use personal protective equipment. Regular safety drills would constantly be demonstrated. Signs would be used to warn staff and/or visitors that are not involved in laboratory work of dangerous places. Building managers would develop evacuation procedures to handle emergency situations and building structure would be designed to make ease of evacuations.

Impacts on Water and Soil-During the laboratory operation liquid and solid waste generated during laboratory operation and blood, stool and urine samples taken from patients for laboratory test may be freely disposed and may consequently contaminate the nearby water and soil. .Wastewater would be treated to reduce the load of contaminants prior to discharging into the environment.

Impact on air quality -During sample preparation and processing, release of volatile organic materials from laboratory chemicals and wastes, besides waste incineration and other solid wastes may contribute to air pollution. To minimize air pollution appropriate procedure would be followed during ample preparation and processing and wastes disposal. According to WBG EHS Guideline Air Emissions and Ambient Air Quality the following mitigation measures may be implemented to minimize impacts:

- Process modification
- Selection of fuels or other materials, the processing of which may result in less polluting emissions
- Application of emissions control techniques or technology that technical feasibility and cost effectiveness of the available options for prevention, control, and release of emissions
- Efficient incinerator would be used to minimize release of volatile organic gases from hazardous wastes

Impact of None-routine Emergency Events-The existing hospitals and the proposed laboratories would need to have emergency response plan to contain accidents that may arise during none routine events such as fire out break or chemical spill.

Risk due to Laboratory bio-safety issues-As no laboratory has complete control over the specimens it receives, laboratory workers may be exposed to organisms in higher risk groups than anticipated. For the proposed laboratories to be designated as BSL 2, the standards practices indicated in the WHO Bio-safety Laboratory Manual of 2004 and detailed in the impact chapter of this report would have to be respected in order to mitigate the bio-safety risk during the laboratories operation.

Community Health and Safety: community health may be affected due to hazards associated with the laboratories operation. Risk management strategies would be prepared to protect general community from biological, physical, and chemical releases during laboratory operation and WBG EHS Guidelines for Community Health and Safety elaborated in detail in impact

chapter of this report is recommended to be used to minimize impact ensure health and safety of the nearby communities

Cumulative Impact due to Healthcare Waste - If the health facilities in the hospitals fail to follow established guidelines for proper disposal of all types of medical and hazardous waste, the release of health care waste from the hospitals and the proposed laboratories may cause long-term, direct, indirect and cumulative pollution impact on air and adverse health impacts on local citizens. Health care wastes released from the existing health institutions and hospitals would be treated by using high temperature incinerator of high efficiency to minimize cumulative impact.

Decommissioning phase

Decommissioning entails closure of the auxiliary facilities and services such as quarry mines, construction materials storage facilities, leftover materials (sand, cement, iron bars etc..).To minimize impacts during decommissioning it important to prepare environmentally management plan that would guide the contractor on how to safely demolish the laboratory building and facilities and safely dispose demolished wastes.

ESMF Implementation Arrangement

Environmental and Social Screening: Federal Ministry of Health (FMOH) would carry out environmental and social screening on the sub projects and would submit it to Environment, Forest and Climate Change Commission (EFCCC) for approval. In case where an ESIA has to be carried for sub-projects, the Regional Environment, Forest and Climate Change Commission (REFCCC) would review the ESIA reports, to ensure that all environmental and social impacts have been identified and that effective mitigation measures have been proposed, before issuing the environmental clearance certificate. REFCCC would supervise compliance to the national regulations and guidelines of the regional laboratories by conducting statutory review of environmental/social screening and ESIA reports of the sub-projects to ensure that all the environmental concerns are mainstreamed into the sub-project activities to minimize negative impacts. World Bank would also oversee compliance of the WB Safeguard Policy the time of implementation of sub-projects.

The public health infrastructure directorate (PHID) of the FMOH is mandated to prepare plans, coordinate project programs and action plans, and ensure the amendments on construction design by taking into account environmental management plans, health and safety standards for contractors. PHID would also organize environmental and social development safeguards committee to assist sub –project implementation.

Regional health bureau (RHB) follows up the environmental and public health aspect of the project, to maintain the hygiene, sanitation and public health services, provision of drinking water supply and management of solid and liquid waste are up to the required standard so as to maintain conducive environment for patients, communities and construction workers during the project implementation.

The respective REFCCC would follow the compliance of the World Bank safeguard policies at each project sites in collaboration PHID/FMOH, and RHB.

Environmental Audits

An environmental and social audit will be conducted for eight BSL 2 laboratories which are already constructed by Global Funds before equipping the laboratories using the audit checklist annexed as annex 7. The objective the audit is to gather environmental information about an organization, a facility, or a site, to verify whether, or to what extent, they conform to specified audit criteria of World Bank. In addition, term of reference for the audit to be conducted annexed here (annex 8).

Capacity Building

Awareness raising and project launching workshop, training of trainers on ESMF implementation and monitoring on social and environmental screening of sub-projects would be provided to the experts of MOH, EPHI and the regional bureaus. Annual review workshops, supervision and monitoring would be conducted. Summary of cost estimated to build capacity of institutions that would implement the ESMF is estimated to be about.**265, 000 US$.**

1. Introduction

1.1 Background

Ethiopia has a population of around 105 million, and is the second-most populous country in Africa after Nigeria. The government of Ethiopia has spent huge resources in the past two decades to strengthen health system and have achieved significant gains in improving the health status of Ethiopians. To this effect, Ethiopia has done well in meeting most of the MDG targets.

Although tangible progress has been made in improving health care and health services, there still exist many challenges in providing health services in satisfactory manner. Some of these challenges include inappropriate safe working environment; insufficient and inconsistent supply chain system; lack of instrumentation with state-of-the–art technologies that provides efficient service and maintenance system; weak or absent of information and Communication Technology (ICT) that enhance network communications and ensure smooth flow of information ; huge gaps in the implementation of Laboratory Quality Management System and attainment of accreditation to ISO standards; weak system for specimen referral linkage and testing services compounded with logistical impediments, and underdeveloped capacity and practices for monitoring and evaluation of the laboratory system's efficiency and effectiveness in addressing the basic needs of health care service delivery and poor public health researches and public health emergency management operations;

Ethiopian has a limited resource to fully address all these challenges. The Government received financial support from the World Bank to implement "Africa CDC Regional Investment Financing Program (ACRIFP)". With the aim to partially address these challenges .The main purpose of this project is to promote ''One Health" approach by strengthening the laboratories capacity in prevention, diagnosis and surveillance of both communicable & non-communicable diseases including those of zoonotic nature by constructing laboratories buildings and establishing efficient system that is accessible and affordable to the public and enhance innovation, knowledge sharing and researches. The proposed laboratories will be sited at the periphery of the country and will therefore be able provide service to the communities of the neighbouring countries in tackling possible epidemics and disease outbreaks.

1.2 Objectives of the ESMF

The aim of preparing the ESMF is to track and ascertain proper assessment and mitigation of potential adverse environmental, health and social impacts that may result from the construction activities of the proposed BSL 2 laboratories. The ESMF will also Issues associated to BSL 2 laboratory operations and its waste management. The ESMF is prepared based on the World Bank's environmental and social safeguard policies. The main principle is to prevent & alleviate harms that have both direct & indirect effect on the environment & the public. The ESMF will ensure project activities in all stages of the project phase conform to the World Bank safeguard policies and national policies, regulations and guidelines of Ethiopia.

The specific objective of ESMF is to make sure that all activities undertaken in the project:

- Prevent adverse environmental impacts;
- Enhance positive environmental outcomes;
- Identify, categorize and mitigate negative impacts with appropriate measures,
- Obtain approval of the ESIA report from Environment Forest & Climate Change Commission
- Ensure compliance with the World Bank's environmental safeguards policies.
- Assess capacity building needs and technical assistance to successfully implement the ESMF

The ESMF includes an Environmental and Social Management Plan (EMP) and capacity building measures for environmental and social management. However, it does not include cost estimates to implementing the t proposed mitigation measures.

1.3 Study Methodology

One of the key objectives of the ACRIFP is to provide a screening process for potential environmental and social impacts of the proposed sub-projects and to recommend generic management and monitoring plans for addressing potential negative impacts. In the development of this ACRIFP a high degree of consultation with various key stakeholders has been carried out. The rationale for these consultations was to solicit views of a cross section of key stakeholders, including key officials of government departments who in one way or another are expected in the implementation of the project.

The following methods were used to collect relevant data/information helpful in the preparation of the ESMF document:

- Review of project concept and implementation processes for the proposed project activities-Review of other relevant literature and government regulations and World Bank safe guard policies;
- Field investigation to assess the status of socio-economic and biophysical environment;
- Identification and analysis of generic potential environmental and social impacts likely to result from implementation of the proposed ;
- Identification of appropriate mitigation measures for the negative environmental and social impacts
- Development of an appropriate screening process for the sub-projects;
- Assessment of capacity building needs for the implementation ESMF;

Field assessment was conducted against World Bank environmental social impact assessment checklist and the field visit was carried out between the first weeks of November till end of December 2018 and during the field assessment, an assessment and stakeholder consultation were made and the summary of the findings of the assessment and stakeholder consultation meeting attached as annex 6. The findings from the field assessment, and community and stakeholder consultation are included as environmental and social impacts and mitigation strategies for these impacts are planned in the ESMF.

2. Project Description

The overall aim of the proposed project is to strengthen the Ethiopian heath care system. The project is designed to support the government's healthcare program for the successful implementation of a basic package of minimum health services for beneficiaries through development of well-established healthcare system and strengthening of the Ethiopia Public Health Institute (EPHI) to meet its national and regional mandate. Ultimately, the strengthening of EPHI will allow the government to improve the national laboratory system, national and regional Antimicrobial (AMR) surveillance system and networking, sub-national, national and regional Data Management Centre (DMC) for public health, promote "data sharing and use for action", build resilient public health and emergency management systems, infrastructure, project management and human resource development.

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2.1 Project Development Objective

The Project Development Objective is to strengthen Africa CDC to improve inter-regional networks for timely infectious disease detection and response

2.2 Project Components

The proposed project will support vital institutional capacity-building efforts by the Africa CDC headquarters in Addis Ababa, the SA-RCC in Lusaka, and the Ethiopian and Zambian health authorities**.** The actions supported by ACDCP are organized under three strategic components: (i) Governance and the Legal Framework; (ii) Public Health Assets; and (iii) Human-Resources Development. In each area, complementary actions by the three implementing bodies—the Africa CDC Secretariat and the Ethiopia and Zambia governments—will establish the physical and organizational infrastructure necessary for the Africa CDC to execute its core functions and lay the groundwork for its continued expansion into a continental health institution. The project components described below are designed to leverage network effects and exploit economies of scale to enhance the efficiency of scarce public health resources, overcome national-level capacity constraints, and maximize the positive spillovers produced by integrated transnational

disease surveillance and emergency-response systems. Detailed information on each component and sub-component specific to Ethiopia is described below.

Component 1: Governance, Advocacy, Legal and operational Frameworks

This component covers four key areas: To ensure that the RCC and national legislative frameworks are consistent with institutional structure and core functions of the Africa CDC , the ACDCP will support: (i) the harmonization of laws, statutes, and policies pertaining to the strengthening of the Africa CDC Secretariat, the SA-RCC, and the NPHIs in Ethiopia and Zambia; (ii) the development of a legal framework that allows for the efficient transfer of samples and other project assets, as well as the sharing of information on disease surveillance and outbreaks, and the full implementation of the IHR 2005 among Africa CDC member states; (iii) create a framework for the RCC and RISLNET. So that we have described the Ethiopian component only

The Government of Ethiopia: Sub-Component 2.2

Serving as the Centre of Excellence and Regional Reference Laboratory of the East Africa RISLNET: EPHI and the broader Government of Ethiopia have developed a strategic investment plan to strength its laboratory network with critical investments in new and rehabilitated infrastructure, quality assurance, equipment management, and operations utilizing resources from different sources including the Project. Project support in equipping regional laboratories will facilitate their enrolment and progress in Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA). The Africa CDC will directly benefit from the improved quality of these laboratories both in its continental mission to improve surveillance networks as well as using the laboratories for specific tests from other countries as defined by the agreement between the GOE and ACDC. Regional capacities/activities (goods, technical services, and civil works) to be financed by the project, include, inter alia: (i) the design, construction, equipping and furnishing and maintenance of a Biosafety Level 3 (BSL-3) national reference laboratory (NRL) including a laboratory medical equipment maintenance centre; (ii) establishment of a Proficiency Testing System and panel production for standard quality assurance, biobank centre for reference materials of all sorts, central warehouse to serve as logistics supply hub for Africa CDC and the East Africa RCC countries; (iii) construction, equipping and furnishing of 15 laboratories along Ethiopia's borders (see figure 2); (iv) equipping and furnishing 8 Biosecurity Level 2 (BSL-2) district laboratories

already constructed by the Global Fund (see (see figure 1); and (v) a set (4) of programs designed to improve laboratory capacity building and operational effectiveness.

- **Anti-Microbial Resistance Centre of Excellence:** Following a baseline assessment in Ethiopia which found widespread resistance to commonly used first-line antimicrobials and that antibiotics were widely misused, EPHI has engaged with the Africa CDC's larger AMR initiative through various steps such as piloting an AMR monitoring scorecard. Going forward, Africa CDC has agreed with EPHI that the latter will be developed as a Centre of Excellence/model in AMR prevention and detection in East Africa through the development and rollout of different AMR tools and policies that will generate knowledge and operational experience which will benefit other countries in East Africa and beyond. ***Regional capacities/activities to be financed by the project include, inter alia:*** (i) Piloting the Africa CDC AMR scorecard at large scale in Ethiopia and support its implementation East Africa region; and (ii) Capacity building and provision of equipment and supplies to expand sentinel surveillance sites to create a national AMR network.

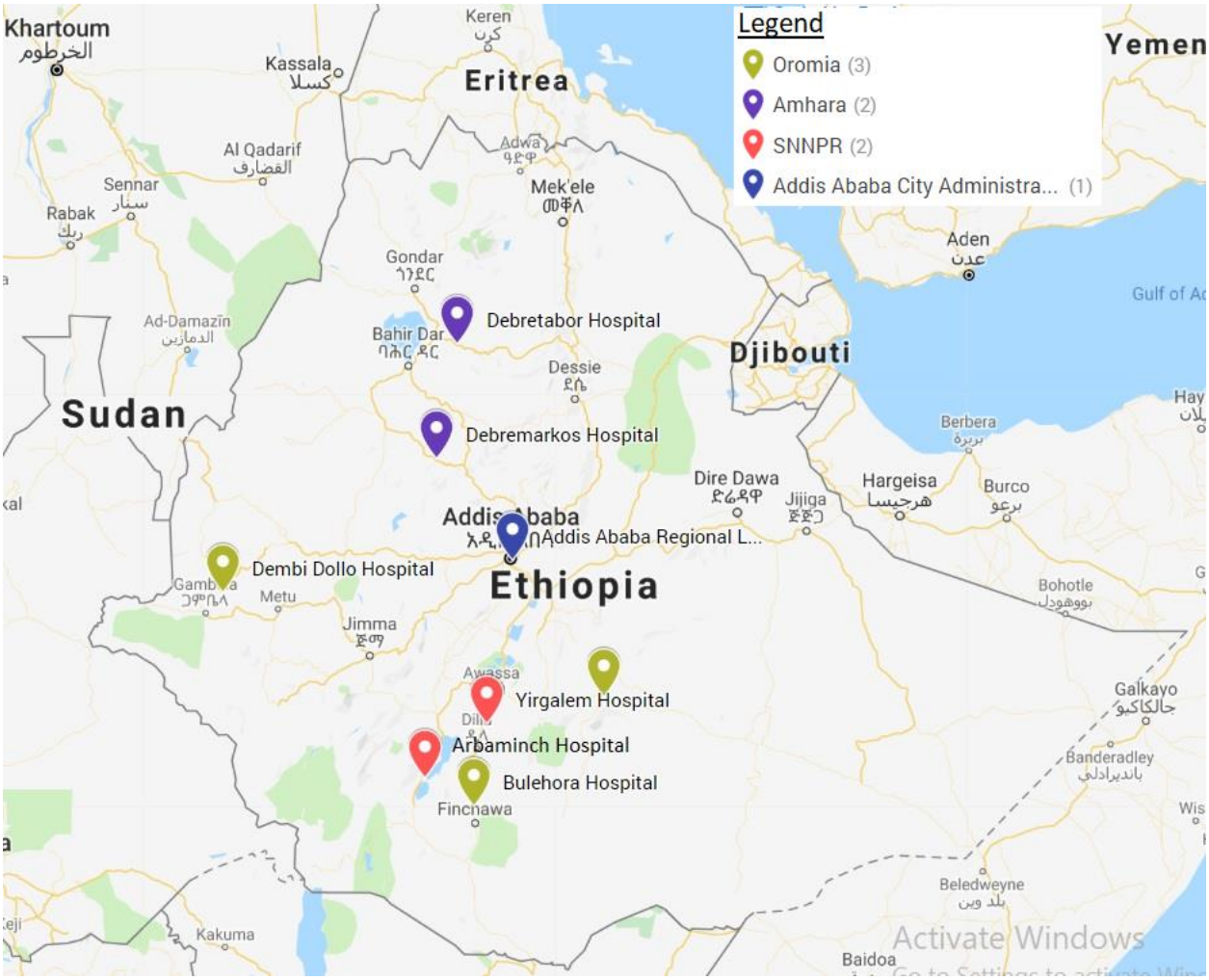

Figure 1: Map of Ethiopia showing location (Regional state) of the BSL 2 Reference Laboratories constructed by Global Fund to be equipped by the project

- **Serving as the Centre of Excellence for integrated surveillance and laboratory data management and disease intelligence:** The national data management centre for health (NDMC) will support ACDC functions on data sharing, building expertise for real time surveillance and reporting, integrated data analysis, evidence translation and in establishing databases and will serve as a regional and continental hub. EPHI will require substantial data processing and electronic communication capacity to fulfil its core function and to contribute to the Africa CDC strategy in establishing a continental data sharing platform. These functions include i) electronic networking of reference laboratories and surveillance sites. ii) Sending and receiving information related to public health emergency management services iii) analysing data and producing regular reports iv) communicating data to national, Africa CDC and international stakeholders v) generate evidence and facilitate evidence translation for

emergency responses and vi) creating interconnected and interoperable emergency, laboratory and AMR data management platform at national level and will be linked with Africa CDC platform. Therefore, the NDMC need to transform EPHI's current paper-based reporting and data processing system into a sophisticated multiuser electronic data processing, storage, retrieval and communication platform. This sub-component will fund goods and services for strengthening the NDMC including the recruitment of an internationally recognized IT consulting firm to oversee i) IT need assessment ii) design a new communications platform iii) procurement and/or development of necessary software and hardware iv) installation and operationalization of the new system v) recruitment and training of EPHI IT staff v) creation of a user-friendly interface and vii) the establishment of a functional communication platform.

Ethiopia's public health system is continually tested by both recurrent and unexpected disease outbreaks and faces the continual challenge of managing the health consequences of natural and manmade disasters, crises, and conflict. While in principle all Ethiopian public health facilities provide Public Health Emergency Management (PHEM) services, the range and quality of such services differs significantly by facility type, region, rural/urban location, and managing authority. Moreover, Ethiopia's proximity to multiple fragile states and its status as a major land and air transportation hub greatly exacerbates its own vulnerability to epidemic disease simultaneously with exposing the African continent to the potential undetected rapid spread of such disease. The subcomponent will enable the EPHI as a public health center of excellence to achieve its goals of detecting, and responding timely to disease outbreaks by financing: (i) surveillance systems strengthening, including at critical Points of Entry (POEs), through developing, adapting, and disseminating guidelines, manuals, and formats; (ii) training the surveillance workforce to the lowest levels; (iii) preventing disease spread through expanding four international travellers' vaccination centres, 22 screening points, and 2 airport isolation sites; (v) strengthening response to public health emergencies through equipping and networking of PHEOCs in Ethiopia; (iv) creating a continent-wide platform for sharing experiences on surveillance and public health emergency response coordination.

Component 3: Human-Resources Development

To fulfil its complex mandate and to ensure that the public health assets described above are fully utilized, the Africa CDC will support the development of diverse and skilled cadre of public health and livestock health workers in line with the One Health Approach. The Africa CDC will build human-resource surge capacity at the national, regional, and continental levels by working

with RCCs and NPHI partners to create a pool of trained African professionals able to respond rapidly and effectively to infectious disease outbreaks and other public health emergencies. Training programs will build on existing courses in member states to increase the number of highly skilled technical experts operating in key areas.

The Government of Ethiopia: Component 3.2

A substantial investment in human capital is critical to ensure effective emergency surveillance and response activities, to fully utilize the BSL 3 and BSL 2 laboratories, for running bio-bank and panel production centres, for building competent workforce for data management and AMR, to ensure smooth and efficient operation of the whole system and to facilitate research collaborations with national, Africa CDC and international partners. Ethiopia's current healthcare workforce is inadequate although the country has been participating in emergency management situations in various African countries. A combination of hiring and training will be necessary to build expertise in major trans-boundary infectious and non-infectious diseases of high significance to Ethiopia and eastern African region and its management, to match the requirements for the proposed investment, for successful implementation of the project and to manage the increasing workload associated with the ACDCP. Knowledge and skill transfer will be facilitated and arranged to ensure that all relevant staff are adequately capacitated with work-related know-how and expertise. For staff retention, the newly enacted Job Grading and Evaluation (JGE) would have significant impact. This component will finance hiring and training of key personnel in critical skills related to laboratory systems, disease surveillance, outbreak investigations, emergency responses, data management, project management and execution, monitoring and evaluation, risk communication.

Cross-Cutting Component: The Contingent Emergency Response Component (CERC): Component 4

During the life of this project, the occurrence of a large-scale disease outbreak or other health emergency could entail deeply negative social and economic consequences. This component will improve response capacity in the event of an emergency following procedures governed by OP/BP 10.00 paragraph 13 (Rapid Response to Crisis and Emergencies). The component will finance the preparation of two Emergency Response Operational Manuals (EROMs) for Ethiopia and Zambia. Technical assistance will be used to prepare these manuals, in coordination with a joint Ethiopian and Zambian team. Triggers for emergency response will be outlined in the EROM; funds will be reallocated from other components to finance the

emergency response; and disbursements will be made against an approved list of goods, works, and services needed to support crisis mitigation, response, and recovery.

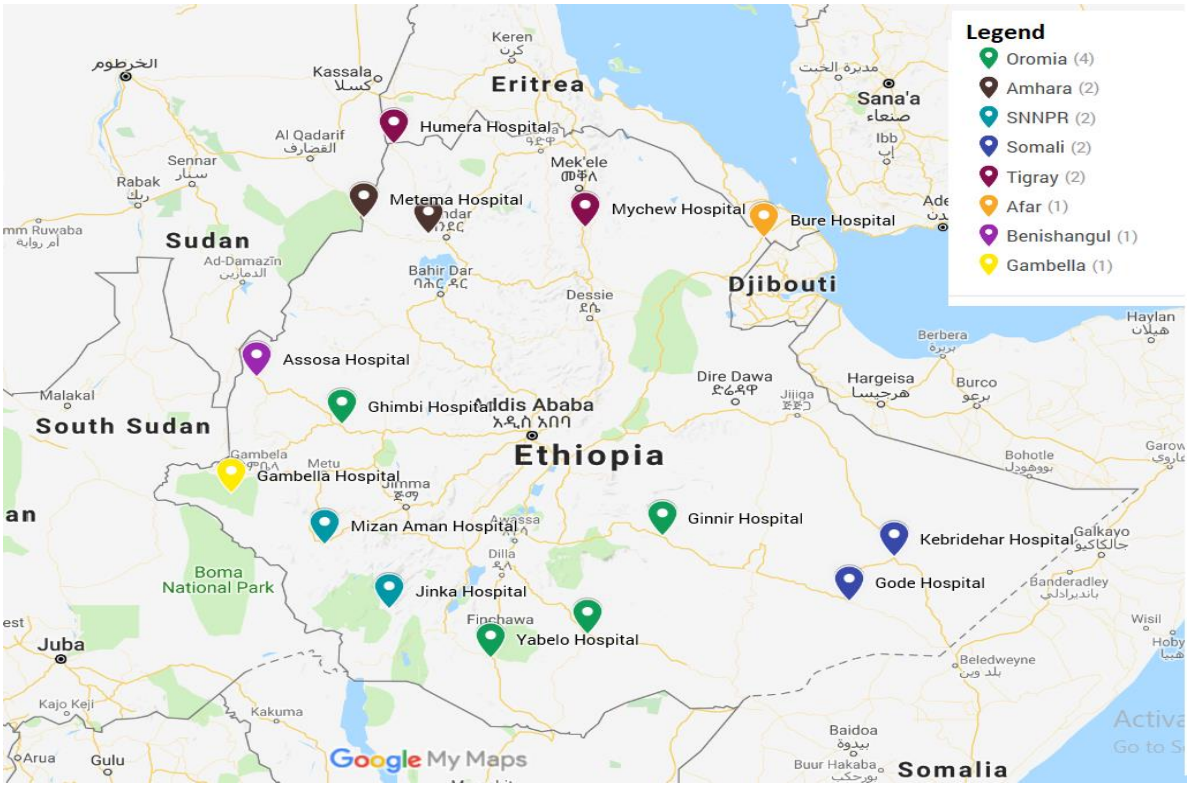

Figure 2: Map of Ethiopia showing location (Regional state) of the BSL 2 Reference Laboratories to be constructed by World Bank Support

The Strategic Plan Management of EPHI (2015/16 to 2019/20), together with the Ethiopian Action Plan for Health Security (2018-2022), is enthused to establish and enhance the level and quality of laboratory service in the country. The FMOH with financial contribution of World Bank has launched “The Africa CDC Regional Investment Financing Program (ACRIFP)” which is part and parcel of Sub-component. The objective of constructing and equipping these laboratories is to boost the capacity and standing of the hospitals to conduct testing, diagnosis and to enhance referral linkages and increase accessibility. At the same time, the laboratories will strengthen and improve the quality of diagnosis and timely detection of contributing agents for disease outbreaks, eventually making quick and effective response to public health threats.

The project is designed to support the government’s healthcare program for the successful implementation of a basic package of minimum health services for beneficiaries through development of well-established healthcare system and strengthening of the Ethiopia Public Health Institute (EPHI) to meet its national and regional mandate allowing the Government to

eventually improve National and Regional Antimicrobial Resistance (AMR) Surveillance System networking, Sub-national, National and Regional Data Management Centre for public health, promote “data sharing and use for action”, Building resilient Public Health and Emergency Management systems, Infrastructure and project management and Human resource development.

3. Social and Environmental Baseline Conditions

3.1 General Environmental Setting

The Africa CDC Regional Investment Financing Program (ACRIFP) project will be implemented in the regions of Tigray (Humera and Maychew Hospital), Afar (Bure Hospital), Amhara (Metema and Gendawa Hospital), Oromia (Yabelo, Negele, Ghimbi and Ginir Hospital), Somali (Kebridehar and Gode Hospital), Benishangul (Assosa Hospital), SNNPR (Jinka and Mizan Aman Hospital) and Gambella (Gambella Hospital). Under this chapter environmental and social base line conditions of the areas that is expected to be influence due to project implementation will be assessed. The main potential safeguard issues expected to arise due to the implementation of this project will be impacts on soil, air, water, and vegetation and the nearby communities during construction, operation and decommissioning phases of the project.

3.1.1 Climate

Ethiopia covers an area of 1,104,300 km^2 with climatic diversity ranging from equatorial rainforest in the south, to the desert-like conditions in Somali and the Danakil Depression in the Afar Region. Ethiopia's topography is very diverse, with elevations ranging from 126m below sea level to 4,500m above sea level. Due to the topographic variation and geographical location, there is a high spatial and temporal variability of rainfall which ranges from 750 mm in Tigray and Amhara to over 1,000 mm in parts of Oromia. Generally, the highland areas receive more rain than the lowlands. The mean range of temperature varies between 15 to 25 °C.

3.1.2 Physical environment

Generally, the physical environment of Ethiopia is mostly dissected by large rivers such as the Baro, Awash, Wabe-Shebelle, Omo-Gibe and Genale-Dawa. Rainfall is erratic and mean annual rainfall is generally less than 900mm and annual mean temperatures are above 18^0C and these areas are mostly faced with recurrent drought.

The main geologic unit of one of the Afar region for example, includes volcanic rocks of the Afar Group and sedimentary of the quaternary age. Outcrops of the Afar group which are dominantly basaltic are found exposed in many areas of the region. Sand, silt, clay and reef limestone of Holocene age cover larger part of the region. Whereas the geologic formation of the other regions such as Somali, Oromia and SNNPR are dominated by alternating limestone, shale, anhydrite, dolomites and marble. Soil types in the later regions are sandy and often coated with reddish soil and calcareous crust typical of desert area. Minerals like edible salt, gold and natural gas also occur in most of the regions.

3.1.3 Biological environment

Generally, vegetation cover of the regions where ACRIFP is planned to be implemented are predominantly Acacia spp., Albizia spp., Erythrina spp., Cordia, Ficus, Belanites aegyptica, Euclea schimperi, Grewia tembensis, G. bicolor, Indigofera spicata, Commiphora, Prosopis juliflora and various species of grasses including Chloris pycnothrix, Hyparrhenia anthistiriodes, H. dregeana, Cenchrus ciliaris, Heterpogon spp., Setaria acromelaena, Aristida kenyensis, Cyondon dactylon, Panicum atrosanguineum, Microchloa kunthii, etc. Natural habitats and national parks that are found in the project areas of these regions include the Awash and Yangudi Rasa National Parks (Afar Region), Yabello Sanctuary in Borena (Oromia Region) and the Babile Wildlife Sanctuary (Somali Region) and Gambella National Park (Gembella Region). In these parks there are number of mammals, birds, reptiles, amphibians, fishes and

invertebrates uniquely adapted to the environment conditions of these regions. Wildlife animals include lion, hyena, leopard, fox, hunting dogs, crocodiles and various types of snakes. There are also a number of birds such as, degodi lark, little winged dove, Somali short billed crombec, Jubaland weaver, little brown bustard and white winged collared dove.

3.1.4 Soil and Geology

The soils found in theproject areas can be classified into five categories. The first category is composed of euritic nitosols and andosols found on the Western (Ghimbi, Beninshangul Gumuz, Gambella, Bure and Negele) and Eastern highlands. The second type of soils, eutric cambisols, ferric and orthic luvisols, are found in the Western Highlands of Tigray such, Maychew. They are highly weathered with a subsurface accumulation of clay and are prone to erosion hazards. The third group of soils is the vertisols/ black cotton found in Humera, Bure, Jinka and Yabelo.. The fourth group is yermosols, xerosols, and other saline soils that cover desert areas of the Eastern lowlands (Kebri Dahr and Gode). Soil characteristics in Afar region is characterized as lithosols, which is mainly found in the Denakil depression.

3.1.5 Water Resources

The project area has abundant surface and ground water resources. The resource is mainly characterized with abundant long range and Tran boundary Rivers. Large areas of the regions are drained by many major rivers. Rivers that cross the ACRIFP project regions include, Awash in Afar and Oromia, Wabi Shebele in Somali, Tekeze in Tigray and Amhara and Baro in Gambella.

3.1.6 Natural vegetation and Forests

Ethiopia's natural vegetation is composed of four biomes. The first is savanna, which is in wetter portions of the western highlands, consists of montane tropical vegetation with dense, luxuriant forests and rich undergrowth. The second biome is mountain vegetation; it comprises montane and temperate grasslands and covers the higher altitudes of the western and eastern highlands. The third biome, tropical thickets and wooded steppe, is found in the Rift Valley and Eastern Lowlands. The fourth biome is desert steppe vegetation, which covers portions of the Denakil depression. There are 58 National forest priority areas in Ethiopia out of which 49 are located in Oromia region accounting for 0.1% of the total surface area of the region. In Amhara region, the natural forest coverage is less than 10% and is heavily degraded as a result of agricultural activities and fuel wood production.

3.1.7 Physical cultural resources

Ethiopia’s rich linguistic and cultural diversity includes tangible and intangible heritage with both traditional and modern cultural expressions. The intangible heritage of Ethiopia is rich with variety of ceremonies, festivals, celebrations and rituals. In addition, eight of Ethiopia's cultural and natural heritage sites are registered on UNESCO's World Heritage Site proving to the outstanding universal value of Ethiopia's heritage.

Among the major physical cultural resources in the ACRIFP areas of Oromia region are: Cafe Tuma the place where Gada laws are drafted and modified; Andode Tuma - the place where Gada laws are publicized or announced; Oda Roba where Gada assemblies, power transfer ceremonies and transition rites took place under sycamore tree (Oda) which is regarded as the symbol of Gada system; mountain Chuqala (Ziquala) where Church of ‘Abo’- an old monastery of over 500 years old, which has a repository of old manuscripts of religious significance written on well prepared goat hides known as ‘birana’; Sof Umar Cave and the Dire Sheik Husen Shrine; Faraqasa which is found in Arsi zone and is the site of spiritual belief centre where eventful ceremony is held every year being attended by thousands of pilgrims coming from all over the country.

The SNNPR is endowed with a number of physical cultural resources such as Natural hot spring; Monasteries and Churches; Historical mosques; Stelae; Caves and forts; Pale anthropological sites; and Cultural and Ethnic attraction. The region has typical ethnical cultural diversity comprising more than 56 distinct nationalities living in different agro-ecology all having their own culture, farming system, indigenous knowledge of managing natural resources. In Tigray region, there are several archaeological places in Laelay-maichew Woreda and around Axum- town. There are also monasteries and beautiful landscape places which are tourism destinations.

3.1.8 Health Services in Ethiopia

Health service provision in Ethiopia includes a wide range of providers in both the public and private sectors, such as public facilities managed by federal, regional state, zonal and woreda administration and private for-profit providers, NGOs, community-based and faith-based organizations and traditional care givers (WHO 2002). Currently there are 290 hospitals, 3962 health centers, and 16547 health posts under the regional and federal government which provides health care services. Ethiopian health care delivery system has three-tier, to deliver essential health services and ensure referral linkages.

The first tier is primary health care unit in woreda health system comprises health posts, health centres and primary hospital. Secondary health service includes general hospitals. Tertiary

facilities form the highest level of healthcare in the country and include Specialist Hospitals, Teaching Hospitals and Federal Referral Hospitals. Environmental and social baseline conditions specific to the regions is described below.

3.2 Environmental Setting Specific to the Regions

3.2.1 Tigray Regional State

Centuries of erosion, deforestation and overgrazing have left the region with dry and treeless plains, hills and plateau. Nevertheless, an amazing landscape of chains of mountains ranging from 3,250-3,500 meters, cliffs, ledges and precipice are natural attractions of the region. The elevation of the region ranges from 550-3935 above sea level. Two altitude extremes: the Tekeze Gorge, 550 meters above sea level and the "Kisad Gudo" peak at 3,935 meters above sea level are among Tigray's natural scenery which is classified into the central highland, the western lowland and eastern escarpments. The climate of the region is characterized as "Kolla" (semi-arid) 39%, "Woina dega" (warm temperate) 49%, and "Dega" (temperate) 12%. The average annual rainfall is between 450-980 mm.

Tekeze and Mereb are international rivers that pass through the State of Tigray with their origin s in the Amhara and Eritrean Mountains respectively. There are small rivers such as Geba, Worii, Berber, Arqoa and Teter, which are suitable for irrigation development. Tekeze is a promising source of hydroelectric power. Lake Ashenge, which is found in the state, is an interesting area for observing birds and for fishing.Elephant, leopard, klipspringer and bush back are among the wild animals that are found in the state. Tigray is one of the richest areas in Ethiopia in mineral resources. Some of the explored metallic minerals of Tigray region State include gold, copper, iron ore, zinc, lead and nickel. Asbestos, Silica sand, Kaolin, graphite, gypsum gemstone, marble, granite slate, limestone and dolomite are among the non-metallic minerals.

Tigray is among the few in the world, frequently mentioned in civilization and cultural lists of humanity for its universally accepted historic sites. The state has some of the most important historical monuments of the continent. It is very well known for its pre-Christian monuments. The Axum obelisks or Steles (2nd century BC), the pre-Axumite Yeha's "Temple of The Moon" (5th century BC), bath and palace of the Queen Sheba and the Ark of the Covenant, are among the most prominent. The Ark of the Covenant, is said to have been brought from the Temple in Jerusalem. Moreover, the region has served as entrance of the two world religions- Christianity in the 4th century AD, and Islam in the 6th century AD into Ethiopia. The mosque of Negash is

also another historical site. There are more than 120 rock hewn churches and caves that serve as monasteries scattered over the mountains of Tigray, containing gold and silver crosses, glittering crowns, manuscripts and stones bearing ancient Sabean inscriptions. These and other cultural heritages are priceless assets of the country. Currently, the population of the Tigray Region is estimated about 5,247,005 in 2017. Regarding heath system, there are 716 health posts, 212 health centers and 34 hospitals. Humera and Maichew towns of the Tigray region are among 15 identified locations for the construction of proposed laboratories in Ethiopia.. According to (CSA, 2017) Humera and Maychew had a total population of 36,074 and 38,839 respectively.

3.2.2 Amhara Regional State

The State of Amhara is topographically divided into two main parts, namely the highlands and lowlands. The highlands are above 1500 meters above sea level and comprise the largest part of the northern and eastern parts of the region. The highlands are also characterized by chains of mountains and plateaus. Ras Dejen (4620 m), the highest peak in the country, Guna (4236 m), Choke (4184m) and Abune – Yousef (4190m) are among the mountain peaks that are located in the highland parts of the region. The lowland part covers mainly the western and eastern parts with an altitude between 500-1500 meters above sea level. Areas beyond 2,300 meters above sea level fall within the "Dega" climatic Zone, and areas between the 1,500-2,300 meter above sea level contour fall within the "Woina Dega" climatic zone; and areas below 1,500 contour fall within the "Kolla" or hot climatic zones. The Dega, Woina Dega and Kolla parts of the region constitute 25%, 44% and 31% of the total area of the region, respectively.The State receives the highest percentage (80%) of the total rainfall in the country. The highest rainfall occurs during the summer season, which starts in mid June and ends in early Sept2. The annual mean temperature for most parts of the region lies between 15^{o}C to 21^{o}C.

The State of Amhara is divided mainly by three river basins, namely the Abbay, Tekezze and Awash drainage basins. The Blue Nile (Abbay) river is the largest of all covering approximately 172,254 Km2. Its total length to its junction with the white Nile in Khartoum is 1,450 Km, of which 800 km is within Ethiopia. The drainage-basin of the Tekeze river is about 88,800 km2. In addition, Anghereb, Millie, Kessem and Jema are among the major national rivers, which are found in this region. Tana, the largest lake in Ethiopia is located at centre of the region. It covers an area of 3,6000 km2. Besides, other crater lakes like Zengeni, Gudena Yetilba, Ardibo (75km2) and Logia (35 km2) are small lakes that are found in the region. Regarding wildlife,

Walia ibex, Semien fox, Gelada-baboon, Grey Duiker, Klipspringer, Hyenas and Corocodile are among the twenty-one species (three endemic) that are found in the region, especially at the Semien mountain national park. Wild fowls, Francolins, Pelicans, Cranes, Ibises, and Stocks are among the birds that are found in the region.

The State of Amhara has mineral resources such as coal, shell, limestone, lignite, gypsum, gemstone, silica, sulfur and bentonite. Hot springs and mineral water are also found in the region. The 12th century Rock-Hewn churches of Lalibela, and the palaces in Gondar the world known heritages of the country. The traditional mural paintings and hand craft, the preserved corpse of the royalty found in the ancient monasteries in Lake Tana, as well as the Semien mountains national park, which shelters the endemic Walia ibex are spectacular tourist attractions, Three tourist attractions found in the region are registered in the UNESCO list of world heritages. Besides these known heritages, the Blue Nile Falls, the caves and unique stones in northern Showa, and the Merto Le Mariam church are special tourist attractions.

About 85% of the people are engaged in agriculture. The region is one of the major Teff producing areas in the country, in addition barely, wheat, oil seeds, sorghum, maize, wheat, oats, beans and peas are major crops produced in large quantities. Cash crops such as cotton, sesame, sunflower, and sugarcane grow in the vast and virgin tract of the region's lowlands. The water resources from Lake Tana and all the rivers found in the region provide immense potential for irrigation development. The population of the Amhara Region is estimated about 21,134,988 in 2017. Regarding health structure, there are 4262 functional health facilities in the region; of these, 3345 are health post, 848 health centers and 69 hospitals. The two towns identified for laboratory construction are Gendewa and Metema, both of which are located in Western part of the region.

3.2.3 Afar Regional State

The Afar national Regional State is situated in the North-eastern part of Ethiopia and has an area of about 94,760 square kilometers. This area of the regional state accounts for 8.4% of the area of country Ethiopia. Afar National Regional State is found in the Great Rift Valley System of Ethiopia. Climate of this region is both Temperatures varies from 25°C during the rainy season (September-March) to 48°C during the dry season (March-September). The average annual rainfall registered for 11 years at Dubti station was 187.9mm. There are about twelve soil types available in the region; and out of these soil types 49% is sandy and rocky. This has resulted in making 70.9% of the total area of the region unproductive; and only about half of this area is

used for grazing for a short period of time during the scanty short rainy season. The climatic condition of the region is mostly hot, desert type and partially dry. As a result the region exhibits high temperature, and low rainfall that is not distributed uniformly. The poor natural resource management practice has contributed to the degradation of the natural vegetation, the loss of the fertile top soil through wind and water erosion; and intensification of desertification.

The Awash River, Mille and Logia which are tributaries of the Awash River traverse the region. Abbe Bil, Afambo and Adebel lakes which are connected to the last section of the river Awash, are found in the region. They form an important habitat for river and Lake Fauna. The lowest point in the Country, Dallol depression that is 126 meters below sea level is found in this region. The lowland areas of Afar are generally below 1600 meters above sea level. The highest peak, mount Mussa-Alle is just 2063 meters above sea level. Yagundu-Ras national park and the Dallol depression are some of the tourist attraction sites in the Afar region. Some of the wild animals in the park include Abyssinian wild ass, Grevy's zebra, beisa oryx, crocodiles, lions, grater kudu, wild (bat eared) fox, wild cat, cheetah, Grant's gazelle, and warthog. Besides, Hadar, which is 4.4 million years old humanoid is found in this region.

Most of the land in the Afar region is used for grazing. However, small of the land in the Awash Valley are used for irrigation and 150,000 hectares of land is reserved for future development of large scale irrigation. The afar pastoralists are suspicious of any externally driven project since previous irrigation developments have displaced them to the surrounding rangelands. Such displacement of the Afar pastoralists has been compounded by the spread of Prosopis spp., from the farms into the surrounding rangelands. This plant was originally introduced to stabilize the banks of irrigation channels has now infested about 700,000 hectares

Afar pastoral community is leading a communal life (using natural resources communally) moving from place to place in search of water and grazing. The life of the people of the region depends on its animal wealth and the natural resources like grazing and water. However, the animal production and husbandry practice in the region is not properly managed in line with the availability of grazing and water distribution. Agriculture such as production of maize, beans, sorghum, papaya, banana, and orange is also practiced. Cotton production is also typical to the region. Commercial activities such as production of salt are another area of occupation.

The state of Afar has mineral resources such as Salt, Potash, Sulfur, Manganese, Bentonite, Aluminium, Marble, Gypsum and Petroleum are possible major resources of the region. In

Argoba special woreda of Afar region there are tombstones and funeral sites that have unique and vivid artistic engraving and old-age mosques with unique early Islamic architecture. These sites are located in Medina, Gacheni, Sherifoch and Chenokebeles of the woreda. Similarly in Mesgido Kebele of Chefraworeda, a Mosque established in 1880 by Haji Amin Kebir has remained a center of religious festive and prayer. The population of the Afare Region is estimated about 1,812,002 in 2017. Regarding health structure, In Afar regional state there are 325 health post, 105 health centre and 6 hospitals. It has one regional laboratory located in Semera town and the new laboratory will be constructed in Bure town.

3.2.4 Somali Regional State

The State of Somali has a very large area size ranking second next to Oromiya. At present the state comprises 9 administrative zones and 49 woredas. This Region is located in the eastern and south eastern part of Ethiopia. It has an estimated area of about 250,000 square kilometers. The topography, agro climatic and agro-ecology of Somali Region similar to that of Afar except that in Somali Regional State, land is relatively fertile and water availability is not scarce compared to Afar. Similar to Afar region most of Somali Region is arid and semi-arid. The majority of the region has an altitude of 900 meters above sea level and in some areas the altitude reaches 1600 meters. Of the total area size of the State approximately 80% is flat & 7% mountainous. Regarding climate, 80% of the region is classified as "Kolla" (lowlands), 5% highland ("Dega"), and 15% of the area fall under temperate ("Woyna Dega") category. The maximum temperature reaches 32-40°C. In the temperate ("Woyna Dega") areas the temperature is within 20-28°C. The mean annual rainfall of the State is estimated to be 300-500 mm. Somali Region is the largest pastoral regions, with a population of about four million people (Devereux, 2006). The Regional Disaster Prevention and Preparedness Bureau (DPPB) of the Somali State divide the region into 17 ‘food economy zones’. Of these, eight are categorized as ‘pastoralist’ and six are ‘agro-pastoralist’ and three are agricultural zone.

Uunlike Afar Somali region have many rivers (Wabeshebele, Genale and Weybe Rivers) that can be harnessed to expand irrigation and sustainably produce food crops to pastoral and agro-pastoral communities of the region. Most of the people of the state of Somali mainly earn their livelihood by rearing livestock. Some people in the region also practice crop production as well. The major crops cultivated in the region are sorghum and maize. Wheat and barley are also harvested in a smaller amount each year. Commercial activity is another occupation that is significantly exercised in the region. The state of Somali is known for its livestock resources from which most of the Somali people earn their livelihood. The region is estimated to have

about 15.2 million domestic animals out of which sheep constitute 53% (nearly 8 million in number). Goats and cattle are the second and third most important domestic animals in the region accounting for 20% and 15% respectively. Camels are actually the most important animals in day to day life of Somali pastoralists , and they constitute for about 9% (1.3 million in number). The population of the Somali Region is estimated about 5,748,998 in 2017. In the region there are 1139 health posts, 195 health centers and 9 hospitals. Gode and Kebri dahar are the two towns in the region were the proposed laboratories are going to be constructed. Gode is located in Shebelle zone and has a population of 579,782 in 2015 whereas, Kebri dahar is located in kebri dahar zone and has 1,191,456 populations as of 2017.

3.2.5 Oromia Regional State

Oromia Regional State consists of 12 administrative zones and 180 woredas. Oromia is a region of great physiographic diversity. Its landscape includes high and rugged mountain ranges, undulating plateaus, panoramic gorges and deep incised river valleys, and rolling plains. Mt. Batu 4607 high is the highest peak of the region. Oromia is endowed with varied relief features which in turn accentuate varied climatic condition and other rich natural resource bases. The climatic types prevailing in the region may be grouped into 3 major categories: the dry climate, tropical rainy climate and temperate rainy climate. The dry climate is characterized by poor sparse vegetation with annual mean temperature of 27°Cto 39°C, and mean annual rainfall of less than 450 mm. The hot semi-arid climate with annual temperature varying between 18°Cand 27°C is area of pastoralist and agro- pastoralists where the proposed project is planned to be implemented. It has a mean annual rainfall of 410-820 mm with noticeable variability from year to yea

Awash, Wabe-Shebele, Genale, Gibe, Baro, Dedessa and Guder are major rivers in the region. The crater lakes such as Green Lake, Bishoftu, Kuriftu, Bishoftu-Gudo, Hora-Kilole, Horsa Arsedi, and the rift-valley lakes of Ziway, Abiyata, Shala, and Langano are found in this region. They have immense potential for recreation and fishery development. Oromia is also rich in wild animals. There are around 800 bird species and more than 100 wild animals in the region. Endemic wild animals such as Red Fox and Menelik Bushbuck are found in the Bale mountains national park. The Awash National Park is home to the Oryx, Kudu, Caracal, Aardavark, Colobus Monkey, Green Monkeys, Baboons, Leopard, Klipspringer, Hippo, Seemering's Gazelle, Grevy's Zebra and Cheetah.The Awash National Park has also bird sanctuary some of which include Limburger, Wattle Crane, Angur Buzzard, Verreaux Eagle and long eared owls. Water Fowls, Shore Birds and the colorful Ruddy Shelled Duck as well as the endemic Blue-

winged Goose are common in the marshy areas of the park. The hot springs in Walliso and Sodere (about 114 km south west and east of the capital respectively) are popular attraction sites for tourists. The Sof-Omar caves in central Bale, with their galleries of polished white cone and chamber of columns are the incredible natural phenomena of great interest and beauty. The palace of Aba Jifar in Jimma is another historical attraction in the region.

Agriculture is the basis of livelihood for the majority of the population in the region. The region is also endowed with livestock resources, although quality and productivity is very low. Traditional range management practices have deteriorated, and development in the water sector for various purposes has led to the degradation of some wet season grazing areas. Grazing land has been taken away from pastoralists for irrigation and for resettlement. Bush encroachment to the grazing lands is also a serious problem to the farmers in the region threatening their livelihood. Mineral deposits such as gold, platinum, nickel, iron-ore, soda ash, diatomite, limestone, feldspar, silica sand, dolomite, kaolin, granite and other construction materials and precious minerals such as gold and platinum is found in Adola and Laga Dambi (Borena zone) Nejo and Birbir river Valley (Wollega) and Yubdo (Wellega). Mining activities that are ongoing include gold (Borena and West Wellega), soda ash in the Rift Valley, limestone, gypsum and clay soil (Muger), tantalum (at Kenticha) ornamental and construction minerals (in Hararghe and Wellega) and ceramic in Borena.

Two project Woredas of Oromia region are endowed with different tangible and intangible cultural resources. Madda Walabu woreda Madda village (inhabited by an agro- pastoral community) where PAP-LDP is planned to be implemented has significant importance in history of Oromo people. Traditionally, it is believed to be the home and origin of Oromo people. It has thus been serving as a center of the Oromo traditional governance. The place has also served as the center of Gumiigayyoo and the seat for a number of abbaagadaas and abbaamuuda (spiritual leaders) at the time. Even if the Islamic religion is expanding and dominating the area, still today the same ritual and gadaa ceremonies are held annually by all Oromo people from the whole of Borana and Arsi rangeland in this village.

Karjul is another sacred and religious place found in MaddaWalabu at 33 kms west of Bidire town. Karjul is equivalent to the monastery and religious place of Shek Hussein in eastern part of Bale administrative zone. In addition to these historical physical resources, the natural bridge under the Welmal Falls is a wonderful site for its aesthetic value. In Liben woreda, there are 16 different sacred places where the gadaa ceremonies take place. These places are located in 10

different kebeles. They are believed to be sacred and thus protected from any intrusion by customary law. In addition to these places, there are a number of natural and cultural sites including waterfalls, elephant sanctuaries, natural caves and endemic birds. In these woredas there are also historically underserved groups having their own boundary, language, identity, unique culture and practices. These groups are undeserved, very vulnerable and some groups are out casted. The above-mentioned groups in these Woredas are different from the wider communities because they are minorities and historically disadvantaged groups.

According to 2017 estimation the population of the Oromia Region is estimated about 35,467,001. The rural residents of this region accounts for 89.5% of the total. Over 90% of the people of Oromia live in the rural area, and agriculture has remained the source of livelihood for the overwhelming majority of the people. The proposed laboratories will be constructed in Ginir (Bale zone), Yabello (Borena Zone), Negele Borana (Guji zone) and Gimbi (West Welega zone). According to CSA in 2017 Ginir has a population of 32,592, Yabello 28,478, Negele Borena 56,897 and Gimbi 50,000. Regarding health system, the Oromia regional state has 6559 health posts, 1699 health centers and 33 hospitals.

3.2.6 SNNP Regional State

The State of Southern Nations, Nationalities and Peoples' comprise 10% of the total area of the country that is administratively divided in to 9 zones, 72 woredas and 5 special woredas. The State lies in the southern part of the country. The State has an undulating land feature dissected by the Omo river basin into western and eastern parts. The elevation ranges from 376 to 4, 207 meter above sea level. The lowest area and highest peaks in the State is recorded near Lake Rudolf in South Omo and at Mount Goge in North Omo, respectively. About 56 % of the total areas of the Region are found below 1,500 meters elevation, which is categorized largely as hottest low land ("Kolla"). The rest 44% is found in the temperate climatic zone. The mean annual rainfall ranges from 500 - 2,200 mm. Its intensity, duration and amount increases from South to Northeast and Northwest. The mean annual temperature is in general ranges from 15°C to 30°C.

Many perennial and seasonal rivers are found in this State. These include, Omo, Gojeb, Mago, Segen, Woito, Akobo, Dima, Wabi, Wolga, Bilate, and Genale. River. Among the known Rift Valley lakes are Awassa, Abaya, Chamo, Chew Bahir and Rudolf. Gilo River can be utilized to produce food crop and fish and for irrigation and hydroelectric development. There are 23 kinds of wild animals and 300 species of birds. Some of the wild animals found in this region are

Elephant, Lion, Giraffe, Leopard, Zebra, Monkey, Lesser kudu, Water Buck, Corocodile, Rhinoceros, Warthogs, and Buffalo. Some of the major tourist attraction sites of the Region are lakes like Awassa, Abaya and Chamo. Tropical forests such as Kaffecho, Shekecho and Omo best tourist destination sites in the country. The Nechsar, Mago and Omo national parks are also found in this region. The State is rich in natural resources. These include, water, mineral, fauna and flora. Some of the minerals of the region include gold, coal, mineral water, clay, ditomite, scoria, limestone, mica, nickel, iron-ore, and asbestos.

There are about 45 ethnic groups in the Region. Sidamigna Gruagigna,Wolayitagna, Hadiyigna, Keffigna,and Kembatigna are widely spoken language in the region. Other languages such as Gamoigna, Malo, Goffa and Gedeo are also used for communication purposes. The working language of the state is Amharic. According to the 1994 census report, the total population size of the State is 10,377,028 of which 5,161,787 were males and 5,215,241 females. The rural population of the Region accounts to about 93.2% of the total population. North Omo, Sidama, and Guragie are the three zones with the highest number of population. The population is concentrated mostly in eastern, northern and central part of the Region while the western and southern part of the State is sparsely populated. Similar to Oromia region SNNP Regional State has abundant land and Water resource that can be harnessed to improve the livelihood of the region community in general and the pastoral and agro pastoral community in the lowlands of the region in particular. But these resources could not be easily accessed and sustainably exploited especially at the southern lowlands where the pastoralist and agro-pastoralist live to lack of adequate in road infrastructure. Coffee is the most important cash crop. Other major crops of the region include maize, teff, enset, potato, and wheat.

According to 2017 estimation the population of the region is estimated about 19,170,007. Jinka and Mizan Aman are the two towns were the laboratories will be constructed Jinka is located in South Omo zone and Mizan Aman is located in Bench Maji zone. Jinka has a population of 43,000 whilst, Mizan Aman has a population of 72,324 in 2017. Regarding health facilities in the region, there are 3874 health posts, 1123 health centers and 72 hospitals in the region.

3.2.7 Gambella Regional State

Gambella National Regional State is one of the 11 administrative regions. It is located in the south-western part of **Ethiopia** and borders with two other regions namely; Oromia to the North and east and the Southern Nations, Nationalities and Peoples' Regional State (SNNPRS) to the south Sudan and d north Sudan to the west. .Gambella National Regional State has three

administrative zones and 13 weredas With an estimated area of 29,782.82 square kilometers .The three zones in this region are Anyuak zone, Mejeng Zone and the Nuer Zone. Gambela is the historic home of the indigenous Anuak.

The Anyuak zone is the largest in terms of land size but the second after the Nuer zone population wise. The weredas which are found in Anyuak zone include Abob,Gog and Dimma. The people of Anyuak also share Itang special wereda and Gambella Zuria wereda with other ethnic groups of the region. The Mejeng zone is the smallest and less populous zone in the region located in south eastern part of the region. The two woredas in the Mejenger zone are Godere and Mengesh. This zone is mostly flat varying between 400m and 550 meters above sea level. But the eastern fringes in particular towards Mezhenger zone rises to up to 2000 meters. Gambella is rich in water resources. Major rivers in the region include Akobo, Baro and Gilo Rivers in addition to numerous tributaries and lakes. The two important lakes in the sub basin are “Bishan waka” which is in the upper Gilo sub basin in Mengeshi district of Mejengir zone and “Tata Lake in the lower sub basin of Gog district of the Agnya zone. Wild animals such as Gosh, monkey, elephants and *Bekeken* are available in the region. The region has huge potential of fishery, gold and oil resources.

Gambella Region is endowed with abundant water resources. Similar to Oromia region Gambella Regional State has abundant land and Water resource that can be harnessed to improve the livelihood of the community in region . However, these resources could not be easily accessed and sustainably exploited to improve the livelihood of the people due to lack of adequate in road infrastructure. The Gambella economy depends largely on farming, fishing, animal rearing and mineral resources. Fishing in this region becomes a vital source of income to many people in Gambella. In addition to that, most of people in Gambella earn their living by producing crops. Furthermore, most farmers in Gambella grow maize but few grow sorghum along the Gilo and Baro rivers. Farmers sell some of their produces and transport them to urban markets in exchange for money. Livestock rearing is predominantly practiced in Akobo, Jikawo, Lare, Mattaar, and Wanthoa weredas and some farmers in Gog, Jor and Abobo weredas also practice animal rearing.

Gambella is rich in minerals some of which are yet to be extracted. An open pit and alluvial gold mine have been in existence for decades in Dimma wereda. The Dimma gold mines continue to provide invaluable income to the people of Gambella as well as miners from Southern Nations Nationalities and People’s State. Oil field has also been explored. The Gambella town is a

separate woreda and also the capital of Gambella region. Gambella town is located in Anyuak zone. According to the 2007 Census conducted by the Central Statistical Agency of Ethiopia (CSA) Gambela Region has total population of 307,096, consisting of 159,787 men and 147,309 women. Region is mainly inhabited by various Nilotic ethnic minority populations, Anuak Mezhenger as well as some Omotic groups (Kafficho, Shakacho), Afro-Asiatic populations (Amhara , Oromo, Kambaata),Tigrawai, and other ethnic groups predominantly from southern Ethiopia. According to 2017 estimation the population of the Gambela region is estimated about 435,999. Regarding health facilities in the region, there are 132 health posts, 31 health centres and 4 hospitals available.

3.2.8 Benshangul Gumuz Regional State

Benishangul-Gumuz (BSG) is located in the north western part of the country created from the western most portion of Gojjam province, and the north-western portion of Welega Province. . Benishangul-Gumuz region is sub divided in three zones and twenty one woreda administrations i.e. Kemashi zone (5 woredas), Assosa zone (9 woredas) and Metekle zone (7 woredas). The ethnic groups include Berta, Amhara, Gumuz, Oromo), Shinasha and Agaw-Awi . Main languages are the Berta, Amharic, Gumuz, Oromo, Shinasha and Awngi. fire.

About 77.4 percent of the region's land mass is bushes and shrubs land and 11.4 percent of forest land. Cultivated land and grazing land constitutes about 5.3 percent, 3.2 percent and 2.3 percent, respectively. The vegetation in this region can be classified into eight types, namely: dense forest, riverine forest, broad-leaved deciduous wood lands, acacia woodland, bush land, shrub lands, Boswellia wood land and bamboo thickets (INBAR, 2010). Environmental and natural resource degradation is the major concern in this region consequently affecting the livelihoods of the people. The problem of deforestation, particularly bamboo degradation is serious problem in Benishangul Gumuz region. A significant decline in lowland bamboo is mainly associated with human interference. The forest cover change was induced by factors such as traditional agricultural production system, improper grazing system, illegal logging and wild.

The economic activities in the region are predominantly agricultural with livestock being of limited importance. Although there is high potential for agricultural development, traditional farming practices and inadequate involvement of women in all aspects of development compounded with other factors have considerably affected the performance of the region's agricultural production and productivity. Subsequently, abundant rural households have been

subjected to food deficit and challenges in feeding their family. Besides agriculture, other means of livelihood are trade and traditional gold-washing in some rivers. Even though there were inspiring developments there is still inadequate infrastructure and logistical constraints in terms of transportation and communication. The limited development of infrastructure is reflected in the region's healthcare, and education system among other social services. Unemployment, lack of knowledge and access to alternative on-farm and non-farm income generating opportunities, poor access to improved health services and limited social and economic infrastructure, broadening the vulnerability of rural households in general and women headed households in particular. In general, chronic food insecurity has remained a critical development challenge for the region for many decades.

The region is endowed with fertile land suitable for high value crops, livestock, apiculture, fishery, minerals like gold and marble, and economically important trees like bamboo and incense. Livestock production is important means of livelihood in the region next to crop production. It is important sources of food, cash income, and assets to buffer against shocks. The region is rich in minerals such as blue-marble found in Gumuz area. The region is gaining importance due to the ongoing construction of the he Grad Millennium Dam aimed to alleviate the power shortage of the country and its neighbors such as Sudan and Djibouti. Gold mining is common e Gumuz area. This is because of their access to areas which are rich in alluvial gold. The people of Benshangul Gumuz practice mixed farming system, involving both crop production and livestock rearing activities. According to the Central Statistical Authority (CSA) (2007) report the region had about 0.4 million cattle, 0.3 million goats, 0.1 million sheep, and nearly one million poultry. Assosa is the largest and the capital city of Benshangul Gumuz region. It is also the project site for the laboratory construction. According to 2017 estimation the population of the Benshangul Gumuz region is estimated about 1,066,001. Regarding health facilities in the region, there are 402 health posts, 49 health centers and 5 hospitals.

4. Legal and Institutional Framework

4.1 Background

In this context, management of the environmental and social effects of ACRIFP-financed activities is assessed based on the existing environmental and social management systems of Ethiopia. In order to assess the adequacy of Ethiopia's legal and regulatory framework, the ESIA looks at the relevant laws and institutions for environmental and social impact assessment and management, along with the roles and responsibilities of institutions involved in the assessment and management processes. The assessment of how these systems function in practice is presented in Section 6 along with a structured gap analysis that identifies inconsistencies between the framework and the national requirements.

4.2 National Regulatory Framework

This section describes the legal and regulatory requirements for environmental impact assessment and management in Ethiopia. Under this section the relevance of these requirements to ACRIFP investments is assessed with due consideration of the requirements and guidelines. There are a number of relevant government policies that are related to giving

direction towards a safe and healthy environment which depends largely on the effective management of the project.

4.2.1 Constitution

The constitution of the Federal Democratic Republic of Ethiopia (FDRE) provides the overriding principles for all legislative frameworks in the country. The right of Ethiopian people to clean and healthy environment is enshrined in the constitution under the following articles.

- **Article 43.** The Right to Development identifies citizens' right to improved living standards and sustainable development and participate in national development and to be consulted with respect to policies and projects affecting their community.
- **Article 44.** Environmental Rights stipulations that all citizens have the right to a clean and healthy environment; and those who have been displaced or whose livelihoods have been adversely affected as a result of state programs have a right to commensurate monetary or alternative means of compensation, including relocation with adequate state assistance.

- **Article 92.** Environmental objectives are identified as government would endeavor to ensure that all Ethiopians live in a clean and healthy environment. The design and implementation of programs would not damage nor destroy the environment. Citizens also have a right to full consultation and to expression of views in the planning and implementation of environmental policies and projects that directly affect them. Government and citizens would have the duty to protect the environment.
- The National Conservation Strategy (1995) takes a holistic view of natural and cultural resources and seeks to present a coherent framework of plans, policies, and investments related to environmental sustainability. The Strategy consists of five volumes: Natural Resource Base, Policy and Strategy, Institutional Framework, Action Plan, and Compilation of Investment Program.

4.2.2 Environmental Policy of Ethiopia

The Environmental Policy of Ethiopia was approved by the Council of Ministers in 1997. It is comprised of 10 sector and 10 cross-sector components, one of which addresses Human Settlements, Urban Environment and Environmental Health. The Policy is based on the findings and recommendations of the National Conservation Strategy of Ethiopia. The Policy contains elements that emphasize the importance of mainstreaming socio-ecological dimensions in

development programs and projects. The goal of the Environmental Policy of Ethiopia is to improve and enhance the health and quality of life of all Ethiopians and to promote sustainable social and economic development through sound management of the environment and use of resources so as to meet the needs of the present generation without compromising the ability of future generations to meet their own needs. The Environmental Policy provides a number of guiding principles that require adherence to the general principles of sustainable development. In particular, the need to ensure that Environmental Impact Assessment (ESIA) completes the following:

- Considers impacts on human and natural environments,
- Provides for early consideration of environmental impacts in project and program design,
- Recognizes public consultation processes as essential to effective management,
- Includes mitigation and contingency plans,
- Provides for auditing and monitoring,
- A legally binding requirement.

4.2.3 Environmental Proclamations Regulation and Guidelines Relevant to this project

Proclamation 513/2007, Solid Waste Management aims to promote community participation to prevent adverse impacts and enhance benefits resulting from solid waste management. It provides for preparation of solid waste management action plans by urban local governments.

Proclamation 299/2002, Environmental Impact Assessment makes ESIAs mandatory for implementation of major development projects, programs, and plans. The Proclamation is a tool for harmonizing and integrating environmental, economic, cultural, and social considerations into decision-making processes in a manner that promotes sustainable development. The proclamation clearly defines:

- Why there is a need to prepare ESIAs,
- What procedure is to be followed in order to implement ESIA
- The depth of environmental impact studies,
- Which projects require full ESIA reports,
- Which projects need partial or no ESIA report,
- To whom the report must be submitted.

Proclamation 300/2002, Environmental Pollution Control requires developmental activities to consider environmental impacts before their establishment. The proclamation requires ongoing activities to implement measures that reduce the degree of pollution to a set limit or quality standard. Thus, one of the dictates of the proclamation is to ensure, through inspection, the compliance of ongoing activities with the standards and regulations of the country through an environmental audit.

Proclamation 295/2002, Establishment of Environmental Protection Organs establishes the organizational requirements and identifies the need to establish a system that enables coordinated but differentiated responsibilities of environmental protection agencies at federal and regional levels. The proclamation indicates duties of different administrative levels responsible for applying federal law.

Proclamation 159/2008, Prevention of Industrial Pollution Regulation: As a follow up to Proclamation 300/2002, this regulation to prevent industrial pollution was developed by the Federal Environmental Protection Authority to ensure compatibility of industrial development with environmental conservation. This Proclamation includes comprehensive industrial pollution standards for a range of industrial and mining activities.

Guideline for Environmental Management Plan (draft), May 2004: This guideline outlines measures for preparation of an Environmental Management Plans for proposed developments in Ethiopia and institutional arrangements for implementation of Environmental Management Plans.

Waste Handling and Disposal Guideline, 1997: The Waste Handling and Disposal Guidelines have been in use by health facilities since 1997. The Guidelines are meant to help industry and local authorities handle medical waste situation at the local level.

Proclamation on Expropriation of Landholdings for Public Purposes and Payment of Compensation: Proclamation 455/2005: Prior to this proclamation, no specific legal framework existed relating to expropriation and compensation. As a result, there have been serious shortcomings in the processes associated with land expropriation, resettlement and associated compensation payments in Ethiopia. The proclamation address issues related to Public Domain Entitlement, Property laws, Land asset classification and valuation, customary

laws, Procedures for expropriation, Procedures for grievance redress. The proclamation establishes the legal principles and framework for expropriation and compensation.

Regulation for the payment of Compensation for property Situated on Landholdings Expropriated for public purposes: Regulation No. 135/2007: This regulation describes the detail implementation procedures in when settling issues related to Public Domain Entitlement, Property laws, Land asset classification and valuation, customary laws, Procedures for expropriation, Procedures for grievance redress. The regulation provides the procedures for application of Proclamation No 455/2005.

Proclamation 456/2005 Rural Land Administration and Land Use: The Proclamation regulates use and administration of rural land and recognizes farm, pastoral, semi-pastoral, and communal landholdings. It outlines a grievance mechanism and dispute resolution system. The law requires that all landholdings be issued a certificate in the name of both wife and husband or the name of all joint holders and would be registered in a database. The law provides for the obligation to pay compensation to landholders if the holder is displaced or to provide replacement land with compensation for lost assets. The Proclamation requires that rural landholders expropriated for federal projects must be compensated based on federal compensation laws or, if displaced for regional projects, they must be compensated according to regional regulations. The Proclamation also states that the holder of rural land who is evicted for purposes of public use would be given compensation or would be given substitute land.

Disputes arising from landholding rights are resolved amicably through agreement (an arbitration body to be elected by the parties to the dispute) or in accordance with rural land administration laws of the regional state. The Ministry of Agriculture and Rural Development will be responsible for implementation of this law while regional states are expected to pass region-specific laws with detailed provisions for implementation and appropriate institutional arrangements for application of the regional provisions. Health Sector-Specific Policies, Laws, and Guidelines: The Ethiopian Health Sector Policy emphasizes promotion of occupational health and safety and environmental health.

Proclamation 200/2000, Public Health Proclamation; Public Health Proclamation comprehensively addresses aspects of public health including among others, water quality control, waste handling and disposal, availability of toilet facilities, and the health permit and registration of different operations. The Proclamation prohibits the disposal of untreated solid or liquid hazardous wastes into water bodies or the environment that can affect human health.

Proclamation 189/2010, Ethiopian Food, Medicine and Health Care Administration (FMHACA) and Control Authority Establishment Council of Ministers gives FMHACA the mandate to protect consumer health by ensuring the standard of health institutions and the hygiene and environmental health protection requirements for communities.

Proclamation 661/2009, Food, Medicine and Health Care Administration and Control provides provisions to:

- Ensure proper disposal of expired medicine and foods and raw materials,
- Ensure handling and disposal of trans-regional solid and liquid wastes from different institutions are not harmful to public health,
- Ensure the quality of trans-regional water supply for the public is up to the standard,
- Ensure availability of necessary hygienic requirements in public health institutions,
- Ensure any waste generated from health or research institutions is handled with special care and disposed of according to procedures that meet national standards,
- Ensure that untreated waste generated from septic tanks, seepage pits, and industries is not discharged into the environment, water bodies or water convergences.

National Health Care Waste Management (HCWM) Strategic Action Plan 2015/16-2019/20 focuses on thematic areas:

- Legal and regulatory framework to provide guidance to health care managers on minimum operation requirements and the need to standardize HCWM practices in all healthcare facilities in the country;
- Process of operational research in pollution reduction and adoption of environmentally friendly technologies;
- Conduct behavioural changes targeting patients, care givers, visitors, and the community in the vicinity of health facilities.

Health and Safety Guidelines for Public Health Laboratories in Ethiopia, 2010: provides guidance on laboratory waste disinfectant, handling, and disposal and to serve as a helpful reference and guide for all public health laboratories in the country.

National Hygiene and Sanitation Strategic Action Plan 2015/16-2019/20: This Plan focuses scale up community led and school led total sanitation and hygiene and sanitation marketing, build adaptation and resilience to climate change in health sector. A separate national strategy

is under development to address large-scale and communal off-site sanitation needs in urban areas in Ethiopia.

Medicinal Waste Management and Disposal Directive, 2011 is applicable to (a) disposal of medicinal waste, but not to medical equipment or management of other healthcare waste generated by health institutions; and (b) all governmental, nongovernmental and private organizations involved in medicinal waste handling and disposal. The Directive requires disposal firms to have secured an appropriate disposal site depending on the Environmental Impact Assessment conducted with support of the Federal Environmental Protection Authority. In addition, a disposal firm is required to have all the facility and practice standards prescribed under this Directive.

The Guideline for Waste Handling and Disposal in Health Facilities (2006) was developed to:

- Enable health professionals to protect themselves against health hazards which might be encountered as result of their occupation
- Create awareness among healthcare workers about the importance of safe disposal of waste generated at health facilities
- Prevent and control environmental pollution by waste carelessly disposed of from health facilities;

  Provide technical support to health professionals and environmental health workers engaged in day-to-day health inspection and control activities.

Proclamation 197/2000, Ethiopian Water Resources Management Proclamation ensures that the water resources of the country are protected and utilized for the highest social and economic benefits of all citizens, to supervise that they are duly observed, and to ensure that harmful effects of water are prevented and that management of water resources is carried out properly. This Proclamation protects water bodies from improper disposal of medical waste.
Among other articles, the proclamation clearly indicates requirements on water bank management and prevention of harmful effects on water resources in the articles 24 and 25 of the proclamation. The supervising body (the Ministry Water, Irrigation and Energy), in collaboration and in consultation with the appropriate public body may:

- Delimit the boundaries of the banks of certain water bodies;
- Prohibit clearing and cutting trees or vegetation and construction of residential houses

within the delimited banks of water bodies;

- The appropriate public bodies would, before allowing or causing the founding of towns or villages, request the supervising body for technical advice in order to prevent or avoid damages, adverse impacts or accidents which may occur as a result of floods and other factors related to water.

Labour Proclamation 377/2003: The Labour Proclamation (which was revised in 2003) provides the basic principles which govern labour conditions taking into account the political, economic and social policies of the Government, and in conformity with the international conventions and treaties to which Ethiopia is a party. The proclamation under its Part Seven, Chapter One, and Article 92 of this proclamation deals with occupational safety, health and working environment, prevention measures and obligations of the employers. Accordingly, the Proclamation obliges the employer to take the necessary measure for adequate safeguarding of the workers in terms of their health and safety. Moreover, the Occupation Health and Safety Directive (MOLSA, 2003) provides the limits for occupational exposure to working conditions that have adverse impacts on health and safety.

Ethiopian Water Resources Management Proclamation, No. 197/2000

The proclamation is decreed to ensure that the water resources of the country are protected and utilized for the highest social and economic benefits of the people of Ethiopia, to follow up and supervise that they are duly conserved, ensure that harmful effects of water are prevented, and that the management of water resources is carried out properly. It proclaims that all water resources of the country are the common property of the Ethiopian people and the state. It has provisions on general principles of water use and management, inventory of water resources, professional engagement in water resource management and supply. Among other articles, the proclamation clearly indicates requirements on water bank management and prevention of harmful effects on water resources in the articles 24 and 25 of the proclamation. The supervising body (the Ministry Water, Irrigation and Energy), in collaboration and in consultation with the appropriate public body may:

- Delimit the boundaries of the banks of certain water bodies;
- Prohibit clearing and cutting trees or vegetation and construction of residential houses within the delimited banks of water bodies;
- The appropriate public bodies would, before allowing or causing the founding of towns or villages, request the supervising body for technical advice in order to prevent or avoid damages, adverse impacts or accidents which may occur as a result of floods and other

factors related to water.

Proclamation 200/2000, Public Health Proclamation; Public Health Proclamation comprehensively addresses aspects of public health including among others, water quality control, waste handling and disposal, availability of toilet facilities, and the health permit and registration of different operations. The Proclamation prohibits the disposal of untreated solid or liquid hazardous wastes into waterbodies or the environment that can affect human health.

4.2.4 Environmental and Social Impact Assessment Guidelines and Directives

The former Ministry of Environment Forest Climate Change has published series of ESIA guidelines for the different sectors outlining the key issues, principles, procedures and processes to be adopted and adhered to avoid and/or mitigate potentially negative environmental and social impacts during project planning, implementation and operation by government, public and private entities. Some of the guidelines are generic and applicable in different sectors and there are also sector specific guidelines prepared for key environmental and social issues to adhere during the ESIA analysis in those specific sectors.

Environmental Impact Assessment Guideline, May 2000

The guideline provides the policy and legislative framework, the general ESIA process and key sectoral environmental issues, standards and recommendations for environmental management in key sectors such as agriculture, industry, transport, tannery, dams and reservoirs, mining, textiles, irrigation, hydropower and resettlement projects.

Environmental and Social Management Plan Preparation Guideline, Nov. 2004

This guideline provides the essential components to be covered in any environmental management plan (e.g., identified impacts, mitigation measures, monitoring, capacity building, etc.) Similar guidelines for the different sectors include the following:

- Environmental and Social Impact Assessment Guidelines for Dams and Reservoirs, 2004
- Environmental Impact Assessment Guideline for Fertilizer, 2004
- Guidelines for Social, Environmental and Ecological Impact Assessment and
- Environmental Hygiene in Settlement Areas, 2004

Directive Issued to Determine Projects Subject to Environmental Impact Assessment,

Directive No.1/ 2008: The directive was issued to identify and list out those investment projects subjected to mandatory Environmental Impact Assessment. The regions are entitled to issue similar directive to their own specific cases based on this directive. Extensive list of project types requiring ESIA are provided in this directive

ESIA Procedural Guideline (draft), November 2003: This guideline outlines the screening, review, and approval process for development projects in Ethiopia and defines the criteria for undertaking an ESIA. Similarly, **the ESIA Guideline, July 2000** provides essential information covering the following elements:

- Environmental Assessment and Management in Ethiopia;
- Environmental Impact Assessment Process;
- Standards and Guidelines;
- Issues for sector environmental impact assessment in Ethiopia covering agriculture, industry, transport, mining, dams and reservoirs, tanneries, textiles, hydropower generation, irrigation projects and resettlement;
- Annexes that (i) identify activities requiring a full ESIA, partial measure or no action; (ii) contain sample forms for application; and (iii) provide standards and guidelines for water and air.

4.3 International Environmental Conventions

Ethiopia has ratified several international/multilateral environmental conventions and many of the principles and provisions in those conventions have been well addressed in the national environmental policies and regulations. Some of these conventions include the following:

- Convention on Access to Information, Public Participation in Decision-making and, Access to Justice in Environmental Matters, Done at Aarhus, Denmark, On 25 June 1998,
- Cartagena Protocol on Bio-Safety to the Convention on Biological Diversity
- Convention on Biological Diversity, Rio, 5 June, 1992
- Kyoto Protocol to the United Nations Framework Convention on Climate Change
- United Nations Convention to Combat Desertification
- UN Framework Convention on Climate Change
- Convention for the Protection of the World Cultural and Natural Heritage Paris, 23 November 1972

Ethiopia is also party to the following four international conventions, which directly or indirectly deal with human health and the environment. These include:

- Persistent Organic Pollutants of Stockholm Convention, which tries to completely eliminate organochlorine and other equally dangerous organohalogen chemicals from the earth.
- Bamako Convention, which prohibits the importation of hazardous wastes into, and their movement in, Africa.
- Basel Convention, which strictly regulates the movement of hazardous waste globally. Recently, it has incorporated the prohibition of the importation of hazardous wastes into developing countries from the Bamako Convention.
    - The first Prior Informed Consent or Rotterdam Convention, which tries to ensure that anybody buying a chemical has complete and accurate information about the nature and impacts of that chemical before he/she decides and notifies his/her consent in writing to the exporter.

4.4 World Bank Safeguard Policies

The World Bank Safeguard policies provide guidelines aimed at preventing and mitigating undue harm to people and to the environment, when implementing development projects. As result the World Bank requires environmental assessment (EA) of projects proposed for Bank financing to help ensure that they are environmentally sound and sustainable, and thus to improve decision making. Environmental Assessment is one of the 10 environmental and social Safeguard Policies that WBG uses to examine potential environmental risks and benefits associated with Bank lending operations.

These policies provide a platform for the participation of stakeholders in project design and implementation, and include the following:

During project preparation, the World Bank examines the implications of the proposed project for a series of policies below table 1:

Table 1: World Bank – Applicable Operational Policies, Bank Procedures

Safeguard Policies	Triggered?	Explanation (Optional)
Environmental Assessment OP/BP 4.01	Yes	The project will finance the construction of a BSL 2 sub-national (regi0nal) Reference Laboratory. The proposed project is Category B It triggered OP 4.01. Thus, Environmental and Social Management Plan (ESMP) have been prepared in response to

		OP/BP 4.01 and
Physical and Cultural Resources (OP 4.11)	Yes	The proposed BSL 2 laboratories project is going to be built within the premises of the health facilities, where there are no known physical and cultural heritage sites. However, since excavation will be conducted before constructing the BSL 2 labs building, it will be inappropriate to neglect the possibility of chance finds. Thus, the proposed project will trigger by this project.
Involuntary Resettlement OP /BP 4.12	No	The Bank's policy on Involuntary Resettlement (OP/BP 4.12) has not been triggered as the proposed BSL2 labs will be constructed within the premises of government owned health facilities/ hospitals. As a result, the project is not expected to cause any involuntary resettlement or loss asset.
Natural Habitats OP/BP 4.04	No	The proposed BSL 2 labs project is going to be built in the premises of the health facilities found in predominantly urban core settlement. The project area is devoid of any natural habitat, park or wildlife sanctuaries. Implementation of the project will not affect any natural habitat and hence OP /BP 4.04 will not be triggered by this project.
Forests OP/BP 4.36	No	The proposed BSL 2 project is going to be built in the premises of the health facilities found in predominantly urban core settlement. The project area is devoid of any natural forest and park. Implementation of the project will not affect any natural forest and hence OP/BP 4.36 will not be triggered by this project.
Pest Management OP /BP 4.09	No	The proposed BSL-2 labs project will apply chemicals at Laboratory scale for carrying out chemical and biological experiment and analysis during operation. These laboratory chemicals are essentially not pesticides. The BSL-2 laboratories may also handle experimental vectors in small quantity not amounting pest. Thus, OP/BP 4.09 not triggered.
Indigenous Peoples OP/BP 4.10	No	The project will not trigger OP/BP 4.10.
Safety of Dams OP/BP4.37	No	The project will not trigger OP/BP 4.10.
Projects on International Waterways OP/BP 7.50	No	The project will not trigger OP/BP 4.10.
Projects in Disputed Areas OP/BP 7.60	No	The project will not trigger OP/BP 4.10.

Environmental and Social Assessment (OP 4.01) and Physical Cultural Resources (OP 4.11) of the World Bank Safeguard Policy will be triggered by this project. The project will not trigger the rest of the World Bank Safeguard Policies.

Environmental Assessment (OP/BP 4.01)

The objective of Environmental Assessment is to ensure that project is environmentally sound and sustainable, and that decision-making is improved through appropriate analysis of actions and mitigation of their likely environmental impacts. This policy is triggered if a project is likely to have potential adverse environmental risks and impacts in its area of influence. *Construction and of* laboratory buildings may have negative environmental impacts, which require mitigation. Therefore, in line with this Operational Policy, this environment and social management framework, for screening of the program for Infectious Disease Control Systems Enhancement Project activities and sites has been prepared. According to this sage guard policy, environmental consequences of projects would be recognized early in the project cycle and taken into account in project selection, siting, planning and design. In so doing, adverse environmental and social impacts may be prevented, minimized, mitigated and/or compensated for; and positive impacts may be enhanced. The World Bank's Environmental Assessment includes the process for mitigating and managing environmental and social impacts throughout project implementation using the Environmental Assessment Sourcebook technical guidance. The World Bank's categorization of projects, with respect to significance of environmental impacts is as follows:

- **Category "A":** A proposed project is classified as Category "A" if it is likely to have significant adverse environmental impacts that are sensitive, diverse, or unprecedented. These impacts may affect an area broader than the sites or facilities subjected to the physical works. Environmental Assessment for a Category "A" project examines the project's potential negative and positive environmental and social impacts, compares them with those of feasible alternatives (including the "without project" situation), and recommends any measures needed to prevent, minimize, mitigate or compensate for adverse impacts and improve environmental performance. For a Category "A" project, the borrower is responsible for preparing a report, normally an ESIA (or a suitably comprehensive or sectoral ESIA) that includes as necessary, elements such as environmental audits or hazard or risk assessments.

- **Category "B":** A proposed project is classified as Category "B" if it's potential adverse environmental impacts on human populations or environmentally important areas, including wetlands, forests, grasslands, and other natural habitats, are less adverse than those of Category A projects. These impacts are site-specific; few if any of them are irreversible; and in most cases mitigation measures can be designed more readily than

for Category A projects. Here the assessment also involves examination of the project's potential negative and positive environmental impacts and recommends any measures needed to prevent, minimize, mitigate, or compensate for adverse impacts and improve environmental performance.

- **Category "C":** A proposed project is classified as Category "C" if it is likely to have minimal or no adverse environmental impacts. Beyond screening, no further action is required for a Category "C" project.

- **Category "FI":** A proposed project is classified as Category "FI" if it involves investment of Bank funds through a financial intermediary, in subprojects that might result in adverse environmental impacts.

Environmental and Social Assessment (OP 4.01): This policy requires environmental assessment (EA) of projects proposed for Bank financing to help ensure that they are environmentally sound and sustainable, and thus to improve decision making. According to the WB guideline and the EIA guideline of the Government of Ethiopia the proposed project falls under category B and project under this category will trigger OP 4.01 of the World Bank.

Natural Habitats (OP 4.04): This policy is triggered when there is household based livelihood intervention with the potential to cause significant degradation of natural habitats, directly through construction or indirectly through human activities induced by the project.

The laboratory projects (sub-projects) will be sited in the premises of the already existing hospitals. The project will not cause degradation on natural habitat and is not expected to trigger OP 4.04.

Pest Management (OP 4.09): The policy supports safe, effective, and environmentally sound pest management. This project at any stage of implementation will not use pesticides and therefore will not trigger OP 4.09.

Indigenous Peoples (OP 4.10): The objective of this policy is to (i) ensure that the development process fosters full respect for the dignity, human rights, and cultural uniqueness of vulnerable and historically under-served communities and peoples; (ii) ensure that they do not suffer adverse effects during the development process; and (iii) ensure that such communities and peoples receive culturally compatible social and economic benefits.

No ingenious people will be affected by the project. The Project will not therefore trigger OP 4.10.

Physical Cultural Resources (OP 4.11): The objective of this policy is to assist countries to avoid or mitigate adverse impacts of development projects on physical cultural resources.

For purposes of this policy, "physical cultural resources" are defined as movable or immovable objects, sites, structures, groups of structures, natural features and landscapes that have archaeological, paleontological, historical, architectural, religious, aesthetic, or other cultural significance.

Physical cultural resources may exist at the sites where laboratory building is planned to be constructed. This policy is therefore triggered with the aim to protect the chance finds of the physical and cultural resources

Involuntary Resettlement (OP 4.12): This policy covers not only to physical relocation, but also any loss of land or other assets resulting in: (i) relocation or loss of shelter; (ii) loss of assets or access to assets; (iii) loss of income sources or means of livelihood, whether or not the affected people must move to another location.

This project will be implemented in the premises of the existing hospital and will not cause any displacement of people or will not cause any loss of asset. The project will not therefore trigger OP 4.12.

Projects on International Waterways (OP 7.50): This policy is relevant if a project activity adversely impact on the quality and quantity of water of international waterway shared with one or more countries.

This project is not expected to impact international waterways and will not therefore trigger OP 7.50.

Safety of Dams (OP/BP 4.37): The WB will not finance any new establishment or rehabilitation of large scale irrigation facilities and dams above 15 meter height.

This is not irrigation project and will not therefore trigger OP/BP 4.37.

Forests (OP 4.36): The policy is not triggered as project activities do not have any direct impacts on the forest resources.

Projects in Disputed Areas (OP 7.60): This project will not be implemented in disputed areas and will not therefore trigger OP 7.60.

4.4.1 Comparison of the World Bank Safeguard and National Polices

The national (Ethiopian) requirements for hazardous waste management and occupational health and safety broadly drive from the six basic legislations that set legally binding rules which should be met by the project proponents. This legislation includes Proclamation 300/2002 on Environmental Pollution Control, Proclamation 513/2007 on Solid Waste Management, Public Health Proclamation 200/2000, Food Medicine and Health care Administration and Control Proclamation no.661/2009, Ethiopian Water Resources Management Proclamation, No. 197/2000 and the FDRE Labour Proclamation no. 377/2003 which are briefly reviewed in the preceding sections.

From the perspectives of hazardous waste management generated from health care facilities such as the proposed BSL 2 laboratory, the significant national laws that set the key requirements involve the Public health proclamation 200/2000 and the Food Medicine and Health Care Administration and Control Proclamation no.661/2009. According to the Public Health Proclamation 200/2000, any solid, liquid and other wastes generated from hospitals (i.e. health care facilities) should be handled with special care and their disposal procedures should meet the standards set by the public health authorities. Moreover, the Food, Medicine and Health Care Administration and Control Proclamation no.661/2009 of Ethiopia stipulates that handling and disposal of solid and liquid wastes derived from different institutions must not be harmful to public health; emphasis is on ensuring the availability of necessary hygiene requirements in controllable health-related institutions. In addition, it indicates that any waste generated from health care facilities must be handled with special care and their disposal procedures must meet the standards set by the relevant executive organ.

To enforce these framework laws of the proclamations, the FMoH and the Food Medicine Health Care Administration and Control Authority has issued two important pieces of documents that elaborate and describe the requirements for Health Care Waste Management at national level. These are the Ethiopian Health Care Waste Management National Guideline (November 2008) and the Ethiopian Medicines Waste Management and Disposal Guideline (August 2011). These directive and guideline documents set the national minimum practices that health care facilities should apply in managing their health care wastes.

On the other hand, the IFC EHS (World Bank Group) and WHO guidelines related to health care facilities are usually considered as bench mark International Good Practice Standards. More specifically, in relation to the proposed BSL 2 Laboratories, the WHO Laboratory Biosafety

Manual (third edition, 2004) and the IFC EHS guideline for Health care Facilities appear to be directly applicable as international best practice requirements to the proposed BSL 2 laboratory project.

A comparison of the detailed requirements of the International best practice standards (i.e. the WHO and IFC EHS guidelines indicated above) with the national guidelines for health care waste management reveals that there is a great similarity in the set of requirements for the approaches, methods and procedures outlined for managing the health care wastes. The health care waste minimization, segregation, colour coding & collection, packaging, storage, sterilization, handling, transport and final disposal requirements of the FMoH Health Care Waste Management National Guideline are broadly identical to those specified in different sections of the WHO and IFC EHS guidelines. Therefore, a comparison of the National HCWM requirements with the International best practice standards do not show any major gap in addressing the proper handling of the highly infectious waste anticipated to be generated by the proposed BSL 2 laboratories.

Regarding emission levels released from Health Care Facilities, the above-mentioned national guideline for HCW doesn't set standards for emission released from medical waste incinerators and associated waste water treatment facilities. As a matter of fact, there is no such emission standard for medical waste incinerators and effluent treatment plants set by the competent national authorities (i.e. EPFCCC, MoH). However, there are such standards that can be drawn from International best practices. For example, according to the UNEP-POPs-BAT/BEP Guideline for Waste Incinerators, it is stated that with a suitable combination of primary and secondary measures, PCDD/PCDF performance levels in air emissions no higher than 0.1 ng I-TEQ/Nm3 (at 11% O2) are associated with best available techniques. It is also noted that best available techniques for discharges of waste water from effluent treatment plants are associated with PCDD/PCDF concentration levels well below 0.1 ng I-TEQ/l. Accordingly, this is taken as the performance standards for air effluent emissions from incinerators and waste water treatments of HCF associated with best available techniques. On the other hand, the IFC EHS guideline for Health Care Facilities also provides emission levels for air and effluent releases as shown in the following table 4 (*Air Emission Levels for Hospital Waste Incineration Facilities).*

5. Environmental and Social Impacts and Mitigation Measures

5.1 Positive Impacts

Most of the impacts of the Africa CDC Regional Investment Financing Program will be positive and include improvements in health and socio-economic conditions. At the time of construction/refurbishment of the labs the nearby communities will benefit from short term job opportunities such as procurement of goods and services to the technicians and labourers engaged in the construction activities. From past experience the community feel they are most of the time marginalized in terms of job opportunities during construction and implementation of new projects. This will create hostile relationship between the project and the community. To minimize such hostile relationship it will be important to give priority to local contractors and

workers especially the youth job opportunities during the construction and operation of the sub project

Similarly, the sub- project when it will be made operational will improve the services of the health sector as follows.

- **Improvement of the Ethiopian health sector:** The project will contribute to improvements in health conditions in Ethiopia through increased provision of and access to health care and laboratory and diagnostic services;
- **Contributes to HSTP of FDRE:** up on finalization the laboratories will contribute positively to the realization HSTP, which is the first phase of 20-year health sector strategy called 'Envisioning Ethiopia's Path to Universal Health Care through strengthening of Primary Health Care';
- **Centre of excellence:** the project will help FMOH/EPHI in achieving its vision of becoming centre of excellence in public health research, laboratory capacity building and public health emergency management in Africa;
- **Strengthen national public health surveillance system:** the laboratory network will facilitate the national emergency response system, by providing quality laboratory result to priority diseases identified for the surveillance system, TB, HIV, polio, Measles, Influenza, Dengue fever etc.
- **Improve detection capacity of antimicrobial resistant microbes:** The laboratories will also enhance the performance of the public health laboratories of Ethiopia to detect and further perform molecular detection of antimicrobial resistant microbes in a well-designed and internationally accepted laboratory setups. In addition, the effort will enhance the already established 15 surveillance sites of Ethiopia.
- **Contribute to Global and Regional Health Objectives:** the project will contribute to national and regional as well as global public health security agendas, by improving the provision of robust laboratory service while contributing to public health emergency response and management. The effort will be fostered in terms of regional cooperation for public health laboratory network to add up to the efforts on control of diseases, by creating an African network of laboratories for prevention and control of trans-boundary diseases;
- The project will include **establishment of a regional training center**, formulation of joint training plans, and conducting joint human resource training assessments for

regional training and capacity building. Short- and long-term training programs for staff development in laboratory and diagnostic skills will be implemented and staff will have access to higher level professional training.

- **Enhance diagnostic service for vulnerable and** underprivileged communities and the regions that needs special assistance
- **Strengthen the public health referral system of Ethiopia by** reducing the burden of referral linkage and socioeconomic cost.
- Provide access to routine laboratory diagnostic service to people in neighbouring countries such as Kenya, Sudan, South Sudan, Eritrea, Somalia and Djibouti.

5.2 Negative Impacts and Proposed Mitigation Measures

5.2.1 Impacts Specific to Proposed Project

The proposed laboratories will be constructed within existing hospital compounds. Therefore, new and temporary access roads and changes in natural ground slopes and landform are unlikely to occur. Nevertheless, the project will generate adverse impacts associated with construction of the new laboratories and laboratory operation activities. Many of the negative impacts during construction will be minor, short term and localized whereas impacts from laboratory operation activities due to the release of medical waste could be sometimes severe and long term if proper mitigation measures are not introduced to minimize them. To avoid, minimize, and/or compensate adverse impacts it is necessary to formulate mitigation measures. The mitigation measures identified in this section may not be enough to address the adverse impacts of the specific sub-projects but only guide the implementing organizations and project units to identify appropriate mitigation measures.

Salient practices from the World Bank Group Environmental, Health, and Safety Guidelines, OSHA Laboratory Safety Guidance, and WHO Laboratory Bio-safety Manual will be adopted in handling health care waste. The guidelines and manual would be referred from time to time for detail information so that the end users will have clear information about the environmental and safety issues associated with the proposed project.

5.2.1.1 Impact due to Faulty Planning Phase (Preconstruction Phase)

Impact due to Design Fault

During design phase, the layout of the proposed laboratories may not meet the standard of the laboratories facilities infrastructure requirements and due to this the laboratory personnel may

be exposed to infectious diseases and occupational health hazards.. To minimize these types of health impacts the laboratory layout would ensure enough space for the personnel to have safe working environment, and waste disposal system. The EHS Guidelines for facility design and WHO Laboratory Biosafety manual third edition include information relevant to management environment, health and safety issues associated with laboratories. These guidelines are applicable for planning new laboratory facilities to minimize impacts as follow:

5.2.1.1.1 WBG EHS Guidelines for Facility Design

The EHS Guidelines for facility design include information relevant to management of EHS issues associated with laboratories which includes a diverse range of activities involving a referral hospital; inpatient and outpatient facilities. These guidelines are applicable for planning new laboratory facilities. These guidelines advise that design and functional layout of laboratory would ensure the following:

- Separation of clean / sterilized and dirty / contaminated materials and people flows;
- Development and inclusion of adequate disinfection / sterilization procedures and facilities;
- Adequate space for the storage of recyclable materials (e.g. cardboard and plastic) for pickup;
- Ventilation systems that provide isolation and protection from airborne infections;
- Design of water systems to provide adequate supplies of potable water to reduce risks of exposure waterborne pathogens;
- Provision of hazardous material and waste storage and handling areas;
- Selection of easily cleaned building materials that do not support microbiological growth, are slip-resistant, non-toxic, and non-allergenic, and do not include volatile organic compound (VOC)-emitting paints and sealants.

5.2.1.1.2 WHO Laboratory Biosafety Manual for BSL 2 laboratory design and facilities

In designing a laboratory and assigning certain types of work to it, special attention would be paid to conditions that are known to pose safety problems. These include:

- Formation of aerosols
- Work with large volumes and/or high concentrations of microorganisms
- Overcrowding and too much equipment
- Infestation with rodents and arthropods
- Unauthorized entrance
- Workflow: use of specific samples and reagents.

Design features

- Ample space must be provided for the safe conduct of laboratory work and for cleaning and maintenance;
- Walls, ceilings and floors would be smooth, easy to clean, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors would be slip-resistant.
- Bench tops would be impervious to water and resistant to disinfectants, acids, alkalis, organic solvents and moderate heat;
- Illumination would be adequate for all activities. Undesirable reflections and glare would be avoided;
- Laboratory furniture would be sturdy. Open spaces between and under benches, cabinets and equipment would be accessible for cleaning;
- Storage space must be adequate to hold supplies for immediate use and thus prevent clutter on bench tops and in aisles. Additional long-term storage space, conveniently located outside the laboratory working areas, would also be provided;
- Space and facilities would be provided for the safe handling and storage of solvents, radioactive materials, and compressed and liquefied gases;
- Facilities for storing outer garments and personal items would be provided outside the laboratory working areas;
- Facilities for eating and drinking and for rest would be provided outside the laboratory working areas;
- Hand-washing basins, with running water if possible, would be provided in each laboratory room, preferably near the exit door;
- Doors would have vision panels, appropriate fire ratings, and preferably be self closing;
- At Biosafety Level 2, an autoclave or other means of decontamination would be available in appropriate proximity to the laboratory;
- Safety systems would cover fire, electrical emergencies, emergency shower and eyewash facilities;
- First-aid areas or rooms suitably equipped and readily accessible would be available;
- In the planning of new facilities, consideration would be given to the provision of mechanical ventilation systems that provide an inward flow of air without recirculation. If there is no mechanical ventilation, windows would be able to be opened and would be fitted with arthropod-proof screens;

- A dependable supply of good quality water is essential. There would be no cross connections between sources of laboratory and drinking-water supplies. An anti-back flow device would be fitted to protect the public water system;
- There would be a reliable and adequate electricity supply and emergency lighting to permit safe exit. A stand-by generator is desirable for the support of essential equipment, such as incubators, biological safety cabinets, freezers, etc., and for the ventilation of animal cages;
- There would be a reliable and adequate supply of gas. Good maintenance of the installation is mandatory;
- Laboratories and animal houses are occasionally the targets of vandals. Physical and fire security must be considered. Strong doors, screened windows and restricted issue of keys are compulsory. Other measures would be considered and applied, as appropriate, to augment security;

5.2.2 Impacts during Construction Phase

In the construction activity of the project impacts will be typical of any building construction works and the following are potential impacts related to the construction activities. The impacts listed below could be properly addressed if the contractors sign and collect the environmental guideline annexed to this ESMF (Annex 2)

5.2.2.1 Project Impact on the staff and patients of the existing Hospitals

Construction activities of the proposed laboratory in the premises of the existing hospital, if not properly managed will create risks to patients and staff and may also adversely impact on the existing laboratory diagnosis affecting the day to day operation of the hospital.

To minimize these types of health impacts, WBG EHS Guideline recommend measures to protect workers, patients and community from general site hazards associated with site under construction as follow:

- Restricting access to the site, through a combination of institutional and administrative controls, with a focus on high risk structures or areas depending on site-specific situations, including fencing, signage, and communication of risks to the workers, and patients as well as local community.
- Removing hazardous conditions from construction sites that cannot be controlled affectively with site access restrictions, such as covering openings to small confined

spaces, ensuring means of escape for larger openings such as trenches or excavations, or locked storage of hazardous materials.

5.2.2.2 Impacts on Soil

During construction of the laboratory building excavation of soil and movement of heavy vehicles and equipment is expected to aggravate soil erosion. Soil may also be contaminated due to fuel and lubricant that will be released from garages, construction machineries and construction wastes. These impacts will be moderate, temporary and localized.

To minimize these types of impacts the following mitigation measures are proposed to be implemented.

- Light construction machinery would be used and excavation would be strictly carried out within the space provided in the layout;
- Fuel and lubricants would be carefully collected and disposed in an environmentally safer way at the site designated for this purpose;
- Erosion would be minimized by rescheduling for the construction to carried out during the dry season and by contouring ,steep channel and slopes, mulching to stabilize exposed areas and by re-vegetating areas around the site.

5.2.2.3 Impact on Vegetation

Some vegetation within the existing hhospitals may need to be cleared to construct the new laboratory building as well as access road to the construction sites.

To minimize these types o**f impacts**

- **Limit ext**ent of trees and vegetation removal
- Tree planting to compensate losses during construction.

5.2.2.4 Impact on Landscape

Piles of construction wastes and packaging materials may affect the scenery of the hospital and also restrict peoples' movement within the premises of the hospital.

To minimize impact

- The construction wastes and packaging materials would be regularly collected, transported and properly disposed on a site designated for this purpose.

- Establishing waste management priorities at the outset of activities based on an understanding of potential Environmental, Health, and Safety (EHS) risks and impacts and considering waste generation and its consequences
- Avoiding or minimizing the generation of waste materials, as far as practicable and where waste generation cannot be avoided , recover and reuse wastes

5.2.2.5 Impacts on Water resources

Nearby rivers, streams and springs may be polluted and silt may be deposited in the river courses due to the construction wastes, on-site makeshift toilets, fuel and lubricant from garages and construction machineries and sediments that may be generated due to movement of vehicles. For sites with water shortages, such impacts could overburden the already available water source for the community living around the project site. The nature of these impacts will be moderate, localized and short term.

To minimize these impacts, construction wastes would be regularly collected and disposed off and lubricant and oil released from garages and construction machineries would be contained and properly disposed off on a site designated for this purpose. Construction and decommissioning activities may also include the generation of sanitary wastewater discharges in varying quantities depending on the number of workers involved. Adequate portable or permanent sanitation facilities serving all workers would be provided at all construction sites. Sanitary wastewater in construction and other sites would be managed using septic systems. The WBG EHS guideline recommended the septic systems to be:-

- Properly designed and installed in accordance with local regulations and guidance to prevent any hazard to public health or contamination of land, surface or groundwater.
- Well maintained to allow effective operation.
- Installed in areas with sufficient soil percolation for the design wastewater loading rate.
- Installed in areas of stable soils that are nearly level, well drained, and permeable, with enough separation between the drain field and the groundwater table or other receiving waters.

5.2.2.6 Impact on Air Quality

Construction activities may generate emission of fugitive dust caused by a combination of on-site excavation and movement of earth materials, contact of construction machinery with bare soil, and exposure of bare soil and soil piles to wind. A secondary source of emissions may

include exhaust from diesel engines of earth moving equipment, as well as from open burning of solid waste on-site. Air pollution from vehicle emissions will be short term, moderate, and localized.

According to the WBG EHS guideline, techniques to consider for the reduction and control of air emissions during construction includes but not limited to:

- Dust suppression techniques would be implemented, such as applying water or non-toxic chemicals to minimize dust from vehicle movements. To minimize air pollution from earthmoving machineries water would be sprayed on access roads and construction sites and loose soil would be compacted and construction machinery would be regularly maintained.
- Selectively removing potential hazardous air pollutants, such as asbestos, from existing infrastructure prior to demolition

5.2.2.7 Impact due to Noise, vibration and Dust

During construction, noise and vibration may be caused by the operation of pile drivers, earth moving and excavation equipment, concrete mixers, cranes and the transportation of equipment, materials and people. This will create occupational health risks to the patients, construction workers and communities. These are risks associated with non-compliance to national labor laws. Dust, vehicular emission, noise and vibration could hamper the health of local residents, hospital community, patients and construction workers. Besides, vibrations due to movement of construction machineries could affect laboratory and hospital equipment and surrounding buildings. In addition, dust from construction could affect the quality of hospitals and laboratory diagnosis services. Thus, existing laboratory equipment would be relocated to the rooms where vibration due to construction machineries is minimal. Some of the WBG EHS guideline recommended noise reduction and control strategies include:

- Planning activities in consultation with local communities so that activities with the greatest potential to generate noise are planned during periods of the day that will result in least disturbance. Construction activities during night time would be avoided.
- Using noise control devices, such as temporary noise barriers and exhaust muffling devices for combustion engines. Noise due to construction machineries would be minimized by introducing silencer to the construction machineries
- Avoiding or minimizing movement through community residence

Workers would wear ear mufflers and other safety equipment's /PPE/. Similarly, the contractor would also be advised to follow the contractor guideline indicated in the ESIA report of the project and the consultant during construction would supervise such guideline are strictly followed by the contractor.

5.2.2.8 Traffic accident due to moving machinery

Material haulage trucks as well as pedestrians around the construction sites may create traffic congestion and may increase of traffic accident. Vehicle traffic and use of lifting equipment in the movement of machinery and materials on a construction site may pose temporary hazards, such as physical contact, spills, dust, emissions, and noise. Heavy equipment operators have limited fields of view close to their equipment and may not see pedestrians close to the vehicle. The WBG EHS guideline (i.e. sub section- moving machineries) clearly sets techniques for the prevention and control of these impacts, these include:

- Planning and segregating the location of vehicle traffic, machine operation, and walking areas, and controlling vehicle traffic through the use of one-way traffic routes, establishment of speed limits, and on-site trained flag people wearing high-visibility vests or outer clothing covering to direct traffic
- Ensuring the visibility of personnel through their use of high visibility vests when working in or walking through heavy equipment operating areas, and training of workers to verify eye contact with equipment operators before approaching the operating vehicle
- Ensuring moving equipment is outfitted with audible back-up alarms
- Using inspected and well-maintained lifting devices that are appropriate for the load, such as cranes, and securing loads when lifting them to higher job-site elevations.

5.2.2.9 Intensification of Malaria

Increased incidence of communicable and vector-borne diseases attributable to construction activities represents a potentially serious health threat to project personnel and residents of local communities. Construction waste and rubble, if not disposed in designated places, is likely to lead to clogging of drainage systems and, in some places may also create stagnant pools of water where mosquitoes, flies and other insects might breed and lead to the transmission of vector-borne diseases as well as affect the general aesthetics of the surroundings. The WBG EHS material provided an integrated control strategy for mosquito and other arthropod-borne diseases that might involve:

- Prevention of larval and adult propagation through sanitary improvements and elimination of breeding habitats close to human settlements.
- Elimination of unusable impounded water
- Implementation of integrated vector control programs
- Promoting use of repellents, clothing, netting, and other barriers to prevent insect bites
- Use of chemoprophylaxis drugs by non-immune workers and collaborating with public health officials to help eradicate disease reservoirs
- Monitoring and treatment of circulating and migrating populations to prevent disease reservoir spread
- Collaboration and exchange of in-kind services with other control programs in the project area to maximize beneficial effects

Furthermore, Mosquito breeding sites such as stagnant pools created due to construction wastes will have to be drained regularly to minimize malaria intensification. The construction wastes would also be regularly collected and transported to the disposal site designated for this purpose and that way aesthetics effect of the surroundings will also improve.

5.2.2.10 Propagation of infectious diseases

Impacts associate with interaction of workers (contractors) with the community may lead to the propagation of infectious diseases. Health hazards typically associated with large development projects are those relating to poor sanitation and living conditions, sexual transmission and vector-borne infections. Communicable diseases of most concern during the construction phase due to labour mobility are sexually transmitted diseases (STDs), such as HIV/AIDS. Contagious diseases may spread due to human contact among the construction working force and community.

WBG EHS recommended interventions for preventing illness among workers in local communities includes:

- Undertaking health awareness and education initiatives, for example, by implementing an information strategy to reinforce person-to-person counselling addressing systemic factors that can influence individual behaviour as well as promoting individual protection, and protecting others from infection, by encouraging condom use
- Training health workers in disease treatment

5.2.2.11 Impact on the existing facilities

Water pipes, telephone and electric cables may be interrupted due to construction. The contractor would relocate water pipes, telephone and electric cables from the construction site. Contingency plan would be prepared to provide water and power to the community during interruption of power and water supply to the community to minimize impact.

5.2.3 Impacts during Laboratory Operation

The expected impacts during the operation phase of the 15 newly constructed BSL 2 laboratories and the 8 equipping BSL 2 laboratories constructed by GF will be addressed below.

5.2.3.1 Laboratory Biosafety Level and Risk Groups

The potential for injuries and illnesses involving routine laboratory operations presents health risk to workers than does the potential for injury and illnesses associated with handling infectious substances at the proposed BSL 1 laboratories would have low risk. Moreover, the combination of utilizing the guidelines, standards, practices and procedures established by the CDC, NIH, Human Health Services, and public health services together with BSL-2 safety equipment and facility safety barriers, results in an overall potential risk of illness to site workers or visitors from operations involving select agents that would be best characterized as minor.

During the 1970s, in an effort to reduce the risks of infection in the laboratory, scientists devised a system for categorizing etiologic agents into groups based on the mode of transmission, type and seriousness of illness resulting from infection, availability of treatment (eg, antimicrobial drugs), and availability of prevention measures (eg, vaccination). The etiologic agent groupings are the basis for the development of guidelines for appropriate facilities, containment equipment, procedures, and work practices to be used by laboratorians. These guidelines, now referred to as biosafety levels 1 through 4, are published and regularly reviewed by the Centers for Disease Control and Prevention (CDC). Biosafety level guidelines recognize that facility design is important in providing a barrier to protect persons working in the facility as well as those in the community. An accidental release of certain airborne infectious agents could be catastrophic.

The essential elements of the biosafety levels for activities involving infectious microorganisms. The levels are designated in ascending order, by degree of protection provided to personnel, the environment, and the community. Standard microbiological practices are common to all laboratories. Special microbiological practices enhance worker safety, environmental protection, and address the risk of handling agents requiring increasing levels of containment. Four BSLs

are described combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations performed, the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity. Risk groups are the result of a classification of microbiological agents based on their association with, and resulting severity of, disease in humans. The risk group of an agent should be one factor considered in association with mode of transmission, procedural protocols, experience of staff, and other factors in determining the BSL in which the work will be conducted.

Biosafety Level 2 practices, equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, and other laboratories in which work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity. With good microbiological techniques, these agents can be used safely in activities conducted on the open bench, provided the potential for producing splashes or aerosols is low. Hepatitis B virus, HIV, the *Salmonella*, and *Toxoplasma* are representative of microorganisms assigned to this containment level. BSL-2 is appropriate when work is done with any human-derived blood, body fluids, tissues, or primary human cell lines where the presence of an infectious agent may be unknown. (Laboratory personnel working with human-derived materials should refer to the OSHA Blood borne Pathogen Standard for specific required precautions).

5.2.3.2 Risks on BSL 2 Laboratories

The principal hazardous characteristics of an agent are: its capability to infect and cause disease in a susceptible human or animal host, its virulence as measured by the severity of disease, and the availability of preventive measures and effective treatments for the disease. Using these agents are assigned to one of 4 classifications, called a risk group (RG). Risk group 1 (RG1) agents are not associated with disease in healthy adults; examples include lab strain *E. coli, Adeno- Associated Virus,* and opportunistic pathogens like *Bacillus subtilis*. Risk group 2 (RG2) agents are associated with human disease but are rarely serious and for which preventative or therapeutic interventions are often available; examples include *Staphylococcus aureus* and *Vaccinia virus*. Risk groups 3 and 4 are reserved for agents associated with serious or lethal disease that pose a high individual or community risk; e.g., Human immunodeficiency virus and Ebola virus, respectively. Biosafety levels are a prescribed set of safety precautions that usually, but not always, correlate to RG. For example, RG1 agents are typically handled

using BSL-1. Sometimes our laboratory methods expand typical routes of exposure introducing new risk, requiring a change in biosafety level.

Primary hazards to personnel working with these agents relate to accidental percutaneous or mucous membrane exposures, or ingestion of infectious materials including accidental needle sticks or cuts or mucous membrane exposures, or ingestion of infectious materials. Extreme caution should be taken with contaminated needles or sharp instruments. Even though organisms routinely manipulated at BSL-2 are not known to be transmissible by the aerosol route, procedures with aerosol or high splash potential that may increase the risk of such personnel exposure must be conducted in primary containment equipment, or in devices such as a BSC or safety centrifuge cups.

Clinical laboratories, especially those in health care facilities, receive clinical specimens with requests for a variety of diagnostic and clinical support services. Typically, the infectious nature of clinical material is unknown, and specimens are often submitted with a broad request for microbiological examination for multiple agents (e.g., sputa submitted for “routine,” acid-fast, and fungal cultures). It is the responsibility of the laboratory director to establish standard procedures in the laboratory that realistically address the issue of the infective hazard of clinical specimens.

BSL-2 recommendations and OSHA requirements focus on the prevention of percutaneous and mucous membrane exposures to clinical material. Primary barriers such as Personal protective equipment should be used as appropriate, such as splash shields, face protection, gowns, and gloves. Secondary barriers, such as hand washing sinks and waste decontamination facilities, must be available to reduce potential environmental contamination. In addition, BSCs (Class I or II) should be used when performing procedures that might cause splashing, spraying, or splattering of droplets. Biological safety cabinets also should be used for the initial processing of clinical specimens when the nature of the test requested or other information suggests the likely presence of an agent readily transmissible by infectious aerosols (e.g., M. tuberculosis), or when the use of a BSC (Class II) is indicated to protect the integrity of the specimen.

The foundations of protective practices in a laboratory lie in an individual’s laboratory experience, technical knowledge, personal work habits, and attitude toward laboratory safety. Unlike administrative controls, which are behaviors dictated by regulation or laboratory policy, the term “protective behavior” is used to define an innate part of each individual worker’s

personal approach to the laboratory environment. As such, “protective behaviors” form the first and most important line of defense against injury or exposure in the biomedical workplace.

5.2.3.3 Occupational Health and Safety and Community Health Concerns

There has been an extremely low incidence of laboratory-acquired infections associated with operations in CDC-registered laboratories since the implementation of CDC-developed guidelines issued in 197. August 2000 reveals substantial reductions in laboratory-acquired infections (LAIs) reported in the 1990s. There is a notable lack of reported cases in the literature relating to laboratory-acquired infections in the United States particularly in the last 10 years. It is known that about 80% of LAIs are caused by inhalation (particularly by aerosols) or direct contact between contaminated surfaces (gloves and hands). The other routes of infection are percutaneous inoculation (needle stick injuries, broken glass injury, and/or animal bites or scratches) and LAIs due to smoking eating, or accidental aspiration through a pipette has now disappeared because of banishment of these practices. Actually, the risk assessment related to microorganisms manipulated in BSL3 laboratories has to consider the possible route of transmission as well as the minimal infective dose for humans. There are several reasons that routine BSL-2 laboratory or similar laboratory operations do not normally produce infectious disease-related health effects to workers, their families, or the public. In general, these are a result of the implementation of the comprehensive WHO, CDC and NIH guidelines that are based upon historical published accounts over many decades of experience in medical and bacteriological laboratories (CDC 1999).

5.2.3.4 Occupational Health and Safety on BSL 2 Laboratories

Occupational health and safety impacts during the operation of the laboratory are common. General health and safety hazards occurring in HCFs include manual handling injuries, such as sprains and strains from lifting materials, falls, trips, and slips; injuries caused by moving objects; and mental stress. HCF health and safety hazards may affect health care providers, cleaning and maintenance personnel, and workers involved in waste management handling, treatment, and disposal. the specific hazards include the following: exposure to infections and diseases, exposure to hazardous materials / waste, exposure to radiation and fire safety.

5.2.3.4.1 Exposure to Infections / Diseases

Health care providers/laboratory workers and personnel may be exposed to general infections, blood-borne pathogens, and other potential infectious materials (OPIM)19 during care and treatment, as well as during collection, handling, treatment, and disposal of health care waste.

According to US OSHA, blood-borne pathogens are pathogenic microorganisms that are present in human blood and can cause disease in humans, including human immunodeficiency virus (HIV), hepatitis B virus (HIB), and hepatitis C virus (HCV). Other potentially infectious materials (OPIM) refers to (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV. Not all Laboratory-acquired infections (LAI) are as overt as puncturing the skin with an infected needle or splashes to the eye or mouth. Aerosols of infectious material can also be a source of LAI. For instance, Brucellosis accounts for 24% of LAI's and 11% of deaths due to these infections, however, the major route of infection was through inhalation of aerosols. Therefore, it is important that all procedures incorporate practices that minimize the creation of splashes and aerosols. Whenever aerosol generating procedures are used, such as: manipulating needles, syringes and sharps; manipulating inoculation needles, loops, and pipettes; manipulating specimens and cultures, the use of a Biological Safety Cabinets (BSC) or other engineering controls greatly reduces exposure to aerosols. BSC are an effective primary barrier against biohazards and there use as a primary containment is an effective mitigation against generated aerosols.

5.2.3.4.2 Exposure to Hazardous Materials and Waste

Laboratory workers may be exposed to hazardous materials and wastes, including glutaraldehyde (toxic chemical used to sterilize heat sensitive medical equipment), ethylene oxide gas (a sterilant for medical equipment), formaldehyde, mercury (exposure from broken thermometers), chemotherapy and antineoplastic chemicals, solvents, and photographic chemicals, among others. In addition to the guidance provided above, hazardous materials and wastes should be handled according to occupational health and safety guidance provided in the General EHS Guidelines.

5.2.3.4.3 Fire Safety

The risk of fire in health care facilities is significant due to the storage, handling, and presence of chemicals, pressurized gases, boards, plastics, and other flammable materials such as

flammable liquids, solid materials and loose electrical connections etc could cause serious fire incidents in BSL 2 laboratories. Flammable liquids are volatile in nature and liberate vapours at ambient or elevated temperatures that can ignite in presence of sparks, hot plates, naked flames or other hot surfaces. A breakdown in the containment of pathogenic organisms may be the indirect result of fire, or electrical accidents. It is therefore essential to maintain high standards of safety in these fields in any BSL 2 laboratory.

5.2.3.5 Community Health and Safety on BSL 2 Laboratories

Community health and safety issues during the construction, operations, and decommissioning of HCFs are generally common to those of most industrial facilities. Health hazards typically associated with large development projects are those relating to poor hazardous/ infectious waste management and communicable diseases of most concern during the laboratory operation phase. Communicable diseases pose a significant public health threat worldwide, and community hazards associated with health care facility environments, particularly related to hazardous health care waste, necessitate that members of the public receive adequate information regarding potential infection hazards within the facility, and at associated waste disposal sites (e.g. landfills).

5.2.3.6 Potential impacts associated with BSL 2 laboratories operation

Primary hazards to personnel working in Biosafety Level 2 is related with indigenous or exotic agents which are highly infectious microorganism, and the common routes of exposure to infectious agents are inhalation, inoculation, ingestion and contamination of skin and mucous membranes. Inhalation hazards may arise during work practices that can generate aerosols. These include the following: centrifugation, mixing, pouring and spilling of fluids. Inoculation hazards include needle sticks and lacerations from sharp objects. Ingestion hazards include the following: splashes to the mouth, placing contaminated articles/fingers in mouth, consumption of food in the laboratory, and mouth pipetting. Contamination of skin and mucous membranes can occur via splashes or contact with contaminated fomites. At BSL 2 laboratory, containment and good laboratory practices reduce this risk, more emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to infectious aerosols.

Workers in BSL 2 laboratory are not only exposed to pathogenic microorganisms, but also to chemical hazards. It is important that they have proper knowledge of the toxic effects of these chemicals, the routes of exposure and the hazards that may be associated with handling and

storage. Material safety data sheets or other chemical hazard information are available from chemical manufacturers and/or suppliers. These would be accessible in each laboratory where these chemicals are used, e.g. as part of a safety manual. Also the quantities of hazardous chemicals stored in the facility at any one time would be just a few litters each of chemical. Even though organisms routinely manipulated at Bio-safety Level 2 are not known to be transmissible by the aerosol route, procedures with aerosol or high splash potential that may increase the risk of such personnel exposure must be assessed in primary containment equipment, or in devices such as a biological safety cabinet (BSC) or safety centrifuge cups.

Some chemicals adversely affect the health of those who handle them or inhale their vapors. Apart from overt poisons, a number of chemicals are known to have various toxic effects. The respiratory system, blood, liver, kidneys and the gastrointestinal system, as well as other organs and tissues may be adversely affected or seriously damaged. Some chemicals are known to be carcinogenic or teratogenic. Moreover, chemical hazards also represent a risk of uncontrolled reaction, including the risk of fire and explosion, if incompatible chemicals are inadvertently mixed. Laboratory personnel may confront hazards posed by forms of energy including fire, electricity, radiation and noise. A breakdown in the containment of pathogenic organisms may be the indirect result of chemical, fire, electrical or radiation accidents. It is therefore essential to maintain high standards of safety in these fields in any microbiological laboratory. If appropriate work processes, engineering, and administrative controls are not in pace to avoid or minimize release of biological agents into the environment, the wastes from laboratory facilities and practices can have serious impact on the community. The proposed laboratories would not use radioactive materials, propellants, or high explosive materials therefore, impacts from these types of materials are unlikely.

5.2.3.7 Strategies to mitigate the potential risks associated with BSL 2 Laboratories

As no laboratory has complete control over the specimens it receives, laboratory workers may be exposed to organisms in higher risk groups than anticipated. The proposed BSL2 laboratories will not be the exception and these possibilities must be recognized in the development of safety plans and policies. The facility, containment devices, administrative controls, and practices and procedures that constitute BSL-2 would be designed to maximize safe working conditions for laboratory personnel working with agents of moderate risk to personnel and the environment. The following standards and best practices are adopted from WHO laboratory biosafety manual, WBG EHS guideline, Occupational Safety and Health

Administration (OSHA) and CDC Biosafety in Microbiological and Biomedical Laboratories 5th Edition to minimize risks associated to BSL2 laboratories

5.2.3.7.1 Microbiological Practices for the BSL 2 Laboratories

- Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
- Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
- Mouth pipetting is prohibited; mechanical pipetting devices must be used.
- Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors would adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
  - Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
  - Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
  - Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
  - Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware would be substituted for glassware whenever possible.
- Perform all procedures to minimize the creation of splashes and/or aerosols.
- Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
- Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods would be used prior to transport:
  - Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.

- Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
- A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. Posted information must include: the laboratory's bio-safety level, supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory. Agent information would be posted in accordance with the institutional policy.

- The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures.
- Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age would be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions would be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.
- The laboratory supervisor must enforce the institutional policies that control access to the laboratory.

5.2.3.7.2 Special Practices for BSL 2 laboratories

- All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.
- Laboratory personnel must be provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory.
- Each institution would consider the need for collection and storage of serum samples from at-risk personnel.
- A laboratory-specific bio-safety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible.
- The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.
- Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.

- Laboratory equipment would be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.
    - Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
    - Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.
- Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety manual. All such incidents must be reported to the laboratory supervisor. Medical evaluation, surveillance, and treatment would be provided, and appropriate records maintained.
- All procedures involving the manipulation of infectious materials that may generate an aerosol would be conducted within a BSC or other physical containment devices.

5.2.3.7.3 Recommended Safety Equipment (Primary Barriers and Personal Protective Equipment) for BSL 2 Laboratories

- Properly maintained BSCs, other appropriate personal protective equipment, or other physical containment devices must be used whenever:
    - Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasal, and harvesting infected tissues from animals or eggs.
    - High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.
- Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Remove protective clothing before leaving for non-laboratory areas, e.g., cafeteria, library, and administrative offices). Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that laboratory clothing not be taken home.
- Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses in laboratories would also wear eye protection.

- -Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection would be based on an appropriate risk assessment. Alternatives to latex gloves would be available. Gloves must not be worn outside the laboratory. In addition, BSL-2 laboratory workers would:
    - Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.
    - Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
    - Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.
- Eye, face and respiratory protection would be used in rooms containing infected animals as determined by the risk assessment.

5.2.3.7.4 Recommended Laboratory Facilities (Secondary Barriers) for BSL2 laboratories

- Laboratory doors would be self-closing and have locks in accordance with the institutional policies.
- Laboratories must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It would be located near the exit door.
- The laboratory would be designed so that it can be easily cleaned and decontaminated. Carpets and rugs in laboratories are not permitted.
- Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment would be accessible for cleaning.
    - Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
    - Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
- Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they must be fitted with screens.
- BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs would be located away from doors, windows

that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.

- Vacuum lines would be protected with liquid disinfectant traps.
- An eyewash station must be readily available.
- There are no specific requirements for ventilation systems. However, planning of new facilities would consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory.
- HEPA filtered exhaust air from a Class II BSC can be safely recirculation back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.
- A method for decontaminating all laboratory wastes would be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

5.2.3.8 Risk of escaping Infectious Agents from BSL 2 Laboratories

In the BSL 2 laboratory there would be infectious agents in storage, diagnosis process or culture. So that there would be a possibility to escape infectious agents BSL-2 laboratories. Potential means for infectious agents to leave the BSL-2 laboratories and possibly cause human health impacts would include five pathways. These are direct transmission, vector-borne transmission, vehicle-borne transmission, airborne transmission, and water-borne transmission.

Direct transmission: would first require a worker to be exposed to an infectious agent. The likelihood of a worker inhaling or otherwise becoming exposed (for example, through cuts in the skin or ingestion) to an infectious agent would be extremely remote. While it would be very unlikely that a worker would be exposed, if exposed with a sufficient dose, it would be possible for them to be carriers for those agents and through direct transmission expose others. This potential is further reduced through the intervention of effective vaccines or therapeutic measures (CDC 1999).

Vector-borne Transmission: Vector-borne transmission can include mechanical or biological transmission of infectious agents. Mechanical transmission includes carriage by crawling or flying insects through soiling of feet or proboscis or by passage of organisms through its gastrointestinal tract, it does not require multiplication or development of the organism.

Biological transmission includes the propagation (multiplication), cyclic development, or a combination of these. The facility would be designed to severely limit the potential for possible vector-borne transmission through insects and rodents.

Vehicle-borne Transmission: The primary concern for vehicle-borne transmission would be by the workers' clothing or skin and hair, as all other materials leaving the BSL-2 would go through a sterilization by autoclave or chemical disinfection. The guidelines established by the CDC and NIH, which would be followed within the proposed BSL-2 facility, are designed to reduce this potential method of transmission. This would substantially reduce any potential for a worker to unknowingly transport infectious microbes from the facility.

Water-borne Transmission. Potable water would not be affected by the implementation of the proposed Action. Facility design features, such as backflow preventers would prevent microbes within the facility from migrating back through the water supply piping to the public. Water exiting through the sink drains would be diverted to a retention tank where it would be disinfected before being sent to the sewer system.

Airborne Transmission: All air leaving the BSL-2 laboratory during normal conditions would exit through ductwork that is HEPA-filtered prior to emission through stacks on the building roof. HEPA filters are rated as 99.97 percent efficient at a most-penetrating "design point" of 0.3 microns diameter as tested by dioctyl phthalate (DOP) particles (NSC 1996). This means that HEPA filters are designed to remove at least 99.97 percent of all the particulates that hit the filters, even in the most-penetrating sizes of 0.1 to 0.4 microns. The remaining particles (less than 0.03 percent) can penetrate or pass through the filters. The number of viable vegetative microorganisms after HEPA filtration would be negligible. Because, HEPA filters have fiber diameters ranging from 0.65 to 6.5 microns in three diameter groupings. The process of aerosol filtration does not simply rely on the size of the opening between fibers but uses a number of physical properties of air movement around fibers to capture the particles.

Since in infectious agents are escaped from BSL 2 laboratories, it may have risks resulting life-threatening for personnel working in BSL 2 laboratory and community. The agents that may cause human disease, present a hazard to workers, and may present a risk of spreading to the community. Duration of the impact would be *long-term/* throughout the entire life of the affected person or short-term depending of the hazard exposed to. The intensity of the impact would be *low* when ''facility design'' and HEPA filters proposed in WHO & WBG EHS Guidelines are adopted. In relation to this, workers at laboratories would always wear PPE while working in BSL-2. The laboratories would also benefit from a long term practices and experience in

performing similar procedures in the existing BSL 2 laboratories through its established system. However, *sensitivity* on the receptors will be *medium*, thereby giving a *moderate* impact *significance*.

5.2.3.9 Mitigation strategies for risk of escaping of infectious agents from BSL 2 laboratories

The following mitigation strategies would be implemented to prevent infectious agents from escaping BSL-2 laboratories

- Laboratory personnel working in BSL 2 would receive specific training in handling pathogenic and potentially lethal agents and would be supervised by competent staff in handling infectious agents and associated procedures.
- Laboratory workers would be trained in equipment operating and handling techniques during operation,
- Equipment would be periodically maintained and calibrated according to manufacture recommendation
- The BSCs' HEPA filters would be tested annually and replaced as necessary.
- Effective vaccines or therapeutic measures would be available for all risk groups
- Trainings would be provided on sample and waste handling, transportation, and storage
- All material would be sterilized by autoclave or chemical disinfection
- Ensure that the facility would be designed to severely limit the potential for possible vector-borne transmission through insects and rodents.
- Ensure that water exiting through the sink drains would be diverted to a retention tank where it would be disinfected before being sent to the sewer system.
- All agents would be contained within the laboratory and biosecurity system would be in place.

5.2.3.10 Impacts on Water and Soil

During the laboratory operation liquid and solid waste generated during laboratory operation and blood, stool and urine samples taken from patients for laboratory test may be freely disposed and may consequently contaminate the nearby water and soil. Pollution impacts of this type are severe but localized. Similarly, ground and surface water resources may be contaminated from discharge of liquid and disposal solid waste, infectious waste, detergents and chemicals used during operation in the laboratories. In addition the seepage from toilet may contaminate ground water resources. Water contamination from this waste may cover large

areas and may be long term. The impacts could be major, long term in nature, and may cover wide areas due to infiltration and transportation.

To minimize water and soil contamination appropriate treatment facilities such as activated sludge in the case of liquid contaminant and sanitary landfill in the case of solid contaminant will need to be provided before they are disposed into the nearby streams and rivers. So that according to WBG EHS Guideline following mitigation measures may also implement:

- Water use efficiency to reduce the amount of wastewater generation
- Process modification, including waste minimization, and reducing the use of hazardous materials to reduce the load of pollutants
- If needed, application of wastewater treatment techniques to further reduce the load of contaminants prior to discharge, taking into consideration potential impacts of cross-media transfer of contaminants during treatment (e.g., from water to air or land),

5.2.3.11 Air Pollution

During sample preparation and processing, release of volatile organic materials from laboratory chemicals and wastes, besides incineration of laboratory and other solid wastes may contribute to air pollution. The impacts could be moderate, long term in nature, and may be localized.

To minimize air pollution appropriate procedure may need to follow for sample preparation and processing, and wastes disposal. According to WBG EHS Guideline Air Emissions and Ambient Air Quality the following mitigation measures may be implemented:

- Process modification
- Selection of fuels or other materials, the processing of which may result in less polluting emissions
- Application of emissions control techniques or technology that technical feasibility and cost effectiveness of the available options for prevention, control, and release of emissions
- Efficient incinerator would be used to minimize release of volatile organic gases from hazardous wastes

5.2.3.12 Impact of air pollution due to waste incineration

In recent years, incineration and combustion of solid waste has become one of the most widely used alternatives for waste management as a strategic option for waste reduction and disposal. In comparison with other waste treatments, incineration presents advantages such as volume reduction, energy recovery, and elimination of pathogen agents. However, the public opinion of most developed countries is frequently concerned about the installation of municipal, hazardous, and medical waste incinerators. 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 polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs, other persistent organic pollutants (POPs) and some heavy metals such as cadmium and mercury (Leech, 1993). MSW incinerators in many countries now apply extensive abatement techniques and comply with emission limits, and in these cases the contribution of MSW incinerators to total emissions of PCDD/Fs and heavy metals has greatly decreased.

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. Evidence for chronic low-level exposures in humans is more limited. In that context, ambient air monitoring is an essential issue to estimate pollutant emissions such as dioxins.

During the operation BSL 2 laboratories, waste are generated and they would be treated using different techniques such as autoclave, chemical disinfectant, incinerators. However, incinerator would contribute to air pollution. So that air quality effects during the operation of the incinerator generate emissions of SO_2, CO_2, CO, NOx, particulates and other toxic substance. 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. To avoid the risk associated with incinerator, it is good that treatment in double chamber Incinerator with good emissions.

The project will adhere to the application of salient practices from the WBG EHS Guidelines for Construction and Decommissioning and the following action will be the mitigation strategies

- Waste segregation for wastes with polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs would be done and these wastes would never be incinerated,
- Materials free of polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs would be purchased, for minimizing the environmental and health impacts.
- Workers will be provided with PPE and the use of PPE would be enforced.
- Improve incinerators and infrastructure for healthcare waste treatment and disposal
- Maintain the existing incinerators periodically
- Applicable national requirements and internationally recognized standards for incinerator design and operating conditions would 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 would be introduced into the incinerator only after the optimum temperature is reached in the final combustion chamber.
- The waste charging system would be interlocked with the temperature monitoring and control system to prevent waste additions if the operating temperature falls below the required limits;
- Formation of dioxins and furans would be minimized by ensuring that particulate control systems do not operate in the 200 to 400 degrees Celsius temperature range; identifying and controlling incoming waste composition; using primary (combustion-related) controls; using designs and operation conditions that limit the formation of dioxins, furans, and their precursors; and using flue gas controls

5.2.3.13 Impact of Improper Healthcare Waste Management

During the operational phase of the BSL 2 laboratories, it is anticipated that solid and liquid wastes are generated on a daily basis. Mainly the wastes to be generated will be domestic waste and infectious/hazardous waste. Since laboratory activities involve certain medical examinations and also there will be a need for usage of different sorts of chemicals or reagents, it can be predicted that different types of hazardous wastes would be generated. Therefore, improper and inadequate waste decontamination and disposal can cause public health risks due to environmental pollution (i.e. impaired air quality, contamination of water courses) and infections when people rummage through improperly dumped infectious waste.

The National FMOH guideline for Healthcare waste management classifies Infectious waste to consist of the following: sharps (needles, scalpels, etc.), laboratory cultures and stocks, blood and blood products, pathological wastes, and wastes generated from patients in isolation because they are known to have infectious diseases. Medical wastes can also include chemicals and other hazardous materials used in patient diagnosis and treatment. These constitute a grave risk, if they are not properly handled, treated or disposed and otherwise are allowed to get mixed with other municipal waste. The types of healthcare waste expected from BSL 2 laboratories will be sharps laboratory cultures, blood and blood products, pathological wastes, liquid hazardous/infectious, chemical waste and nonhazardous wastes see below table 2 for expected wastes from BSL 2 laboratory.

Improper waste collection and accumulation of waste can be cause of infection and may lead to occupational hazard. It is therefore, the collection of waste would be made at least once in 24 hours, and it would be done in such a way to minimize nuisance of smell and dust during collection and all the waste collected must be carried away from the storage site to an approved disposal point. In addition laboratory would have standard operation and decontamination procedure manuals and clearly displayed at appropriate point(s) with the laboratory

Table 2: Waste Expected from the Proposed BSL 2 Laboratories

Type of waste	Waste description
Biohazard solid waste	Items contaminated with blood and body fluids, including cotton, infected blood, patient samples and specimens
Microbiology Waste	Cultures; stocks and microorganisms; dishes and devices used for culture
Pathological waste	Human tissues, organs or fluids; body parts; unused blood products.
Sharps	Needles; syringes; scalpels; blades; glass, etc.
Disposables	Disposables other than sharps, e.g. Gloves, valves, and any other infected plastics
Liquid Waste (hazards &infectious)	Waste generated in the laboratories hazardous and infectious liquid
Chemical Waste	Chemicals used in the production of biological, laboratory reagents; film developer; disinfectants that are expired or no longer needed; solvents; outdated, contaminated and discarded chemicals
Incineration Ash	Ash from the incineration of any biomedical waste

Appropriate technologies and methods would be used to treat and dispose risks due to healthcare waste. The proposed laboratories would adhere to the application of the following guidelines to minimize impact emanating from health care waste.

5.2.3.13.1 Waste Treatment Methods/ Technology for BSL 2 Laboratory

The Ethiopia Healthcare Waste Management National Guideline 2008 categorises HCW in Ethiopia into nine classes. The treatment options are based on the Healthcare Waste Management National Guideline (HCWMNG). In Ethiopia, burning in low-cost incinerators, burying or applying chemical disinfectant of HCW is for the present moment is probably the most affordable and acceptable options for smaller health care facilities. However, this option is not environmentally satisfactory, and would only be considered as a short-term solution. The following HCW treatment technologies /facilities are recommended to minimize HCW impacts.

Steam sterilization (autoclaving): Steam sterilization in an autoclave is one of the most common forms of sterilization. It involves the use of saturated steam within a pressure vessel at temperatures high enough to kill infectious agents in the waste. Sterilization is accomplished primarily by steam penetration. Steam sterilization is most effective with low-density material such as plastics. In general, contaminated items or wastes would be sterilized for 30 minutes at 121°C with a pressure of 106 KPa. Do not begin timing until the autoclave has reached the desired temperature and pressure. Before sterilization, the items to be treated would be decontaminated, cleaned, and dried carefully.

Burning and Incineration: Incineration converts combustible materials into non-combustible residue or ash. Gases are ventilated through the incinerator stacks, and the residue or ash is disposed of in a sanitary landfill or a pit prepared for this purpose (i.e. ash pit). If incinerators are properly designed, maintained, and operated, they are effective in killing organisms present in infectious waste. In health care facilities without an incinerator, burning of paper waste in a protected pit can be used as an alternative short term solution. However, when using this method the area needs to be protected so as to prevent access of an authorized persons or animals.

Thermal inactivation: involves the treatment of waste with high temperatures to eliminate the presence of infectious agents. This method is usually used for large volumes of infectious waste. Liquid waste is collected in a vessel and heated by heat exchangers or a steam jacket that surrounds the vessel. The types of pathogens in the waste determine the temperature and duration of treatment. This method requires higher temperatures and longer treatment cycles than steam treatment.

Gas/vapor sterilization: Gas/vapor sterilization uses gaseous or vaporized chemicals as the sterilizing agents—ethylene oxide is the most commonly used agent.

Chemical disinfection/high-level disinfection (HLD): Chemical disinfection is the preferred treatment for liquid infectious wastes, but can also be used for treating solid infectious waste. Disinfectants are often hazardous and toxic, and many are harmful to the skin and mucous membranes. Users would therefore wear protective clothes including gloves and goggles. Small amounts of disinfectants can be discharged into sewers without pretreatment, provided there is an adequate sewage treatment process; large amounts of disinfectants would never be discharged into sewers. No disinfectants would be discharged into natural water bodies.

5.2.3.13.2 Waste Treatment Methods in Ethiopia by Waste Class

The Ethiopia Healthcare Waste Management National Guideline 2008 categorises HCW in Ethiopia into nine classes. The treatment options are based on the prevailing health systems in Ethiopia as revealed in the Healthcare Waste Management National Guideline (HCWMNG). In Ethiopia, burning in low-cost incinerators, burying or chemical disinfectant HCW is for the present moment probably the most affordable and acceptable options for smaller health care facilities. However, this option is not satisfactory environmentally, and would only be considered a short-term solution to HCW treatment see Annex 11 guideline for waste treatment and disposal.

Non Hazardous Waste (Class 1): These would be separated from other HCW and Non-risk health care waste would be disposed of similarly to domestic garbage and food waste (burning, municipal waste collection, land fill, etc.).

Clinical Waste (Class 2): These wastes would be burnt and buried in protected pits and the waste containers would never be placed in public areas.

Sharps (Class 3): This waste would first be incinerated before being landfilled. In the alternative, they can be encapsulated and then landfilled.

Anatomical Wastes and placentas (Class 4): Anatomical wastes such as placentas can be buried at depths of over 1 metre inside the HCF.

Hazardous pharmaceutical and cytotoxic waste (Class 5): These would be burnt in temperature around and exceeding $1200^{O}C$. If the HCF can afford to build a Cement Kilns, then they can be treated at the HCF, if not, these would be transported to a central treatment centre. These would never be disposed of in sewers or land filled without appropriate treatment.

Highly Infectious Wastes (Class 6): These wastes would be autoclaved at a temperature of 121°C for at least 20 minutes at source. Or it would be treated in a concentrated solution of Sodium Hypochlorite (NaClO) before being disposed with other wastes.

Radioactive Wastes (Class 7): These wastes can be stored in designated rooms cordoned off from access and allowed to decay to background level. Once at background level, the non-infectious radioactive wastes can then be treated the same way as Class 1 HCW while the infectious radioactive waste would be treated the same way as Class 2 HCW.

Waste with high contents of heavy metals (Class 8): This would be treated as a specialised kind of waste and would be collected and stored in a tin container at room temperature and transported to where it will be treated in an environmentally sound manner.

Effluents (Class 9): All effluents in HCFs would be drained to a septic tank or cesspool for both storage and treatment in the compound of the HCF.

Liquid Waste (infectious & chemical wastes): Collected body fluids, blood and other infectious liquids will be treated using 5% sodium hypochlorite (NaOCl –bleach) and drained into septic tank as well as liquid chemical waste will be diluted/neutralized and disposed to the sewer with water.

Handling, Storage and Collection of health care waste: Packaging and storage of special health-care waste consists of leak-proof primary packaging at the source and leak-proof solid containers of secondary packaging for transportation. A colour code of either yellow or red would be chosen for infectious HCW. The World Health Organization recommended colour-coding, to indicate the level of risk is as follows;

According to the national guideline the following coding of health care waste containers will be used:

- **Black:** All bins or bags containing non-risk HCW.
- **Yellow:** Any kind of container filled with infectious HCW, including safety boxes.
- **Red:** Any kind of container filled with heavy metal or effluent.
- **White:** Any container or bin filled with drug vials, ampoules, or glass bottles for glass recycling or reuse. This system is used only where a municipal glass recycling system is available.

Final disposal: The following guidelines would be applied when disposing healthcare waste.

- The recommended types of final disposal methods are: conventional sewer system for discharge of treated liquids and grounded solids; or landfill disposal of treated solids and incinerator ash.
- The Ministry responsible for environment and MOH would ensure that only treated infectious wastes are buried in landfills.

- Burial sites would be fenced to prevent access by community members or animals. Burial would not be used in areas with high water tables. The bottom of the pit would be at least 1.5 meters higher than the groundwater level.
- Facilities would secure the services of reputable waste handlers to ensure, to the extent possible, that final disposal of health care waste is performed according to applicable federal and local regulations.

5.2.3.13.3 WBG EHS Guidelines: "Waste management":

These guidelines apply to both non-hazardous and hazardous waste. They advocate for waste management planning where waste would be characterized according to: composition, source, types, and generation rates. This is essential for laboratory facilities comprised in this project since there is a need to segregate the different categories of waste generated at the laboratory level. These guidelines call for implementation of a waste management hierarchy that comprises prevention, recycling/reuse; treatment and disposal. The guidelines require segregation of conventional waste from hazardous waste streams and if generation of hazardous waste cannot be prevented; its management would focus on prevention of harm to health, safety, and environment, according to the following principles:

- Understanding potential impacts and risks associated with management of any generated hazardous waste during its complete lifecycle.
- Ensuring that people handling, treating and disposing of hazardous waste are reputable and legitimate enterprises, licensed by the relevant regulatory agencies and following good industry practice.
- Ensuring compliance with applicable regulations.

WBG EHS Guidelines for Hazardous Materials Management:

These guidelines apply to projects that use, store, or handle any quantity of hazardous materials, defined as materials that represent a risk to human health, property, or the environment due to their physical or chemical characteristics. The hazardous materials can be classified according to the hazard as explosives; compressed gases, including toxic or flammable gases; flammable liquids; flammable solids; oxidizing substances; toxic materials; radioactive material; and corrosive substances.

5.2.3.14 Impact of Hazardous Laboratory Chemicals and Other Agents

Expired or accidentally spilled hazardous laboratory chemicals will adversely affect human health and the environment if they are not properly managed.

The proposed laboratories would adhere to the application of the following guidelines which represent best practices and experiences in Chemical Hazards management.

WBG EHS Guidelines

Hazardous materials have risk of uncontrolled reaction, including the risk of fire and explosion if they are not properly stored and are inadvertently mixed. 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 would 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

Expired and or spilled laboratory chemicals would be collected and handled in a leak-proof container for transportation. The following guidelines would be followed when disposing hazardous laboratory chemicals:

- Disposal sites would be fenced to prevent access by community members or animals. The disposal site in areas with high water tables. The bottom of the pit would be at least 1.5 meters higher than the groundwater level.
- Facilities would secure the services of reputable chemical handlers to ensure, to the extent possible, that final disposal of the expired chemicals is performed according to applicable federal and local regulations.

5.2.4 Basic Principles and Practices for Effective Healthcare Waste Management in BSL 2 Laboratory

The safe and sustainable management of healthcare waste is a public health imperative and a responsibility of partners working in the health sector. Improper management of healthcare waste poses a significant risk to patients, health-care workers, the community and the environment. (Chartier, 2014). The key to effective management of HCW is identification and segregation of the waste. It ensures that the correct disposal procedures are taken, personnel safety is maintained, environmental harm is minimized and recycling consumes the least resources. This topic focuses on the best practices as regards proper acceptable waste management practices for BSL 2 laboratory based on the standards recommended by the WHO Safe management of wastes from healthcare guideline, WBG EHS Guidelines and Ethiopian Healthcare waste Management guideline and are discussed in this chapter for implementing in the proposed BSL 2 Laboratories.

5.2.4.1 Waste Minimization

The best practice is to ensure that all units in each HCF minimizes their waste generation (all classes of wastes) to the barest possible minimum. Appropriate plans, strategies and actions would be established to ensure adequate HCW minimization at source and encouraging the use of recyclable materials and products.

5.2.4.2 Waste Segregation

Proper segregation of waste at source generation (at each medical unit/department) is essential, efficient and effective in managing HCW. It helps in reducing the quantity of waste requiring treatment prior to final disposal and ultimately reduces the cost of waste treatment/management. Segregation involves putting different classes of wastes into separate and appropriate temporary storage color-coded containers/bags as recommended by the Health Care Waste Management National Guidelines. In essence, waste segregation and waste color coding work hand in hand. The nine categories of HCW would be segregated and color-coded as outlined below in table 3. Please refer to Annex 11 for further information on the nine categories of HCWFor instance, sharps must be put into a separate containers (preferably sharp boxes) from other hazardous wastes as well as non-hazardous wastes. All waste would be fully inserted into the container with no part sticking out. A homogenous segregation format must be practiced across all HCF in order to avoid mistakes during recording, collection, storage, transportation and onward treatment.

5.2.4.3 Packaging

Infectious waste would be contained from its point of origin to the point at which it is treated and no longer infectious. The packaging would be appropriate for the type of waste involved. The following guidelines would be included for packaging sharps and other health care wastes:

- Sharps (sharp items or items with sharp corners) would be placed in rigid, puncture-resistant containers made of glass, metal, rigid plastic, or cardboard.
- Liquid infectious wastes would be placed in capped or tightly stopped bottles or flasks; large quantities may be placed in containment tanks.
- Solid or semisolid wastes would be placed in tear-resistant plastic bags judged by their thickness or durability.
- There would be special packaging characteristics for some treatment techniques: incineration requires combustible containers, and steam sterilization requires packaging materials that allow steam penetration and evacuation of air.

5.2.4.4 Colour Coding

Colour coding is done by using colours to differentiate waste classes from one other. It is efficient and helps in the process of waste segregation at source. It is also simple, easy to use and thus can be understood even by illiterate patients particularly at health posts where illiteracy level is high. Colour coding is one of the efficient ways of achieving segregation of waste and for sorting out items such as paper, plastic, glass and metal for recycling. It is important that all HCF in Ethiopia use the same colour coding scheme as this helps to minimize and avoid a waste class from mixing with other waste classes. This is also advocated in the Ethiopia National Healthcare Wastes Management Guidelines document. As expected, there will be a wider range of waste classes generated at secondary and tertiary healthcare facilities when compared to primary healthcare facilities. Thus is expected that the use of a broader colour scheme be applied at the former when compared to the latter. For the sake of uniformity and homogenous colour coding for SHC must be an expanded version from that used in the Health Posts.

The following guidelines would be included for the color-coding system:

- **Black:** All bins or bags containing non-risk HCW.
- **Yellow:** Any kind of container filled with infectious HCW, including safety boxes.
- **Red:** Any kind of container filled with heavy metal or effluent.

- **White:** Any container or bin filled with drug vials, ampoules, or glass bottles for glass recycling or reuse. This system is used only where a municipal glass recycling system is available.

In resource limited HCFs, red containers can be omitted and heavy metals and other effluents can be handled as any other infectious waste using yellow receptacles. However, heavy metals and other effluents would not be incinerated. Regarding the disposal of pharmaceutical wastes, please refer to the Medicines Waste Management and Disposal Directive 2011. Health workers must properly segregate waste at the point of use and ensure proper segregation bins and safety boxes are available at all injection sites.

5.2.4.5 Labelling

An important aspect of color coding is labelling. All waste bags or containers would be labelled with basic information in the local language of the area where the HCF is located and or in English. Basic label information would include type of waste in the container; name of the ward/facility, date of collection and, warning of hazardous nature. In general, labelling is important in order to

- identify the source of HCW or date of generation in case of an accident or improper segregation of the waste, ensure that the workers responsible for HCW management handle the different types of wastes safely, Ensure that each staff member feels more responsible for what they put into the bag/receptacle
- Ensure that segregation is done properly
- Ensure that Medical Departments gather data on the amount of waste produced in each department.

5.2.4.6 Collection of Healthcare Waste of BSL 2 Laboratory

Collection of waste is extremely important particularly to avoid over spilling of waste out of collection containers. Collection must be done promptly and routinely or as often as required. This will reduce the probability of contaminated wastes coming into contact with the public. Collection of waste must be done by approved and trained personnel fully equipped with appropriate PPEs and conveying machinery such as trollies and carts. BSL 2 laboratory staff must be actively involved in collection of waste as would the waste handlers. They would ensure that their containers/bags (Bins/boxes and collection receptacles) are never more than three-quarter full before sealing them at their points of generation. They would also ensure that such

collection containers are appropriately labelled. See Annex 11 Guidelines for Management of Each Class of HCW.

Table 3: Summary of WHO recommended segregation and collection scheme

Waste categories	Colour of container and markings	Type of container	Collection frequency
Infectious waste	Yellow with biohazard symbol (highly infectious waste would be additionally marked HIGHLY INFECTIOUS.	Leak-proof strong plastic bag placed in a container (bags for highly infectious waste would be capable of being autoclaved).	When three-quarters filled or at least once a day.
Sharps waste	Yellow, marked ***SHARPS*** with biohazard symbol.	Puncture-proof container.	When filled to the line or three-quarters filled.
Pathological waste	Yellow with biohazard symbol.	Leak-proof strong plastic bag placed in a container.	When three-quarters filled or at least once a day.
Pharmaceutical & Chemical waste	Brown, labelled with appropriate hazard symbol.	Plastic bag or rigid container.	On demand.
Radioactive waste	Labelled with radiation symbol.	Lead box.	On demand.
General health-care waste	Black	Plastic bag inside a container or container which is disinfected after use.	When three-quarters filled or at least once a day.

5.2.4.7 Handling

When handling waste, handlers would wear protective clothing at all times including face masks, aprons, boots, and heavy duty gloves, as required.

Sharps:

• When handling sharps, do not recap or bend needles attached to the syringe.

• Immediately place the syringe in a safety box.

• If needle removers are used, needle removal must take place immediately after the injection.

Safety boxes:

- Safety boxes must be fully and properly assembled before use.
- Safety boxes must be sealed and collected when they are ¾ full, and must never be emptied or opened.
- Place sharps containers (i.e., safety boxes) as close to the point of use as possible and practical, ideally within arm's reach.

- Mark or label safety boxes so that people will not unknowingly use them as a garbage container for discarding other items.
- Do not shake safety box to settle their contents and make room for more sharps.
- Do not place safety boxes in high traffic areas (corridors outside patient rooms or procedure rooms) where people could bump into them or be stuck by someone carrying sharps to be disposed of.
- Do not place containers on the floor or anywhere they could be knocked over or easily reached by a child.

Infectious waste bins:

Infectious waste bins would be covered before collection. Bins would be cleaned and disinfected with 0.5% chlorine solution after emptying and before reuse.

5.2.4.8 Waste Storage

Storage is classified into internal and external. Consideration for storage must be based on the classification or type of waste being dealt with and the potential risk of infection to health-care workers and waste disposal staff.

The following rules would be observed for proper storage of HCW in Ethiopia

- Initial packaging and storage would take place where HCW is generated.
- Storage of waste may then be moved to a temporary on-site storage location
- Non-risk HCW would always be stored in a separate location from the infectious/ hazardous HCW in order to avoid cross-contamination.

Internal (Primary) Storage: Internal storage is the temporary placement of waste at the point of generation before transfer to external storage points. A storage location for the HCW would be designated inside the BSL 2 laboratory. The waste in the bin-liners or containers would be stored in a separate area, room or building appropriate to the quantity of waste produced bearing in mind the frequency of collection. Segregation of hazardous waste from general waste would be maintained in storage. They would be planned periodic cleaning and disinfection of temporary storage areas and the containers. The storage time for HCW before it is transferred to external storage facilities would ensure that during cold/rain season 48 hours and during hot season 24 hours.

External (Secondary) Storage: External storage refers to the transit point where waste is stored after removal from primary storage to the time it is collected and transported for

treatment and final disposal. These are locations in special areas or in the grounds of a BSL 2 laboratory where larger containers are used to store waste until it goes for final disposal either on or off-site. The external storage is usually situated within the BSL 2 laboratory. The frequency of removal of waste stored depends on the volume and nature of waste generated Storage is classified into internal and external. Consideration for storage must be based on the classification or type of waste being dealt with and the potential risk of infection to health-care workers and waste disposal staff.

BSL 2 laboratory must designate an area within its premises where waste can be temporarily stored until final collection for disposal and onward treatment. It is expected that BSL 2 laboratory must manage the HCW it generates. Such a general storage location would be located at the back of the facility and away from the view of the public. it is also important to educate patients who patronise the laboratory on how to dispose of certain personal wastes. Patients would be encouraged to dispose of their waste in appropriate manners. For instance, when blood samples are taken, cotton wool is usually given to the patient to cover the puncture. Such cotton wool could be contaminated, and it is important such a waste is disposed for properly. In this case, it would be disposed of in a yellow bag rather than in a black bag.

5.2.4.9 Transportation

A protocol for transportation of infectious substances is annexed (Annex 9). Consideration for transportation must be based on the classification or type of waste being dealt with and the potential risk of infection to health-care workers and waste disposal staff. Transportation is classified into On-site transport and Off-site transport, since the waste generated from BSL 2 laboratory is treated at facility, off-site transport is negligible**.** So that On-site transport involves conveying of wastes from the various points of generation within a laboratory to a temporary storage location also within the same area.

The following would be adhered to when carrying out *On Site transportation*

- Every effort would be made to avoid unnecessary handling of HCW;
- All waste bags would in-place and intact at the end of transportation;
- Carts, containers, or vehicles used for the transportation of health-care waste would not be used for the transportation of any other material;
- Waste that has the potential to leak must be double bagged;

- Waste bags would be placed in containers (e.g. cardboard boxes or wheeled, rigid, lidded plastic or galvanized bins), before being placed directly into the transportation vehicle
- A trolley, bin, or wheelbarrow may be used for transporting safety boxes and bins.
- The collected waste would not be left even temporarily anywhere other than at the designated storage room.
- Containers would be covered with lids during storage and transport.
- Carts would be used for transporting bags of infectious waste within the facility.

5.2.4.10 Collection and treatment of liquid health-care waste

Segregation, minimization and safe storage of hazardous materials are just as important for liquid wastes as they are for solid wastes. Typically, a system of sewer pipes linked to form a sewerage system will collect wastewater from around a facility of BSL 2 laboratory and carry it below ground to a central location for treatment or disposal. This treatment plant is located at a facility, and wastewater collected from medical areas by pipe system and passed into septic tanks. The basic principle of effective wastewater management is a strict limit on the discharge of hazardous liquids to sewers. Chemical waste, such as formaldehyde and glutaraldehyde and pharmaceuticals, would not be discharged into wastewater but would be collected separately and treated as a chemical health-care waste.

Pretreatment is recommended for wastewater streams from departments, and the pretreatment could include acid–base neutralization, filtering to remove sediments, or autoclaving samples from highly infectious patients. Non-hazardous chemicals can be discharged to the sewer without pretreatment. Collected body fluids, blood and rinsing liquids from procedures might be highly infectious so that it would be treated using 5% sodium hypochlorite (NaOCl – bleach) before disposal. Sodium hypochlorite would never be mixed with detergents or used for disinfecting ammonia-containing liquids, because it might form toxic gases. Lime milk (calcium oxide) can be used to destroy microorganisms in liquid wastes with high organic content requiring disinfection (e.g. stool during a cholera outbreak). Onsite treatment of healthcare sewage will produce a sludge that contains high concentrations of pathogens, and would be treated before disposal.

5.2.4.11 Waste Disposal Methods for BSL 2 Laboratory

Disposal of hazardous ash: Fly ash and bottom ash from incineration is generally considered to be hazardous, because of the possibility of heavy metal content and dioxins and furans. It

would preferably be disposed in sites designed for hazardous wastes, e.g. designated cells at engineered landfills, encapsulated and placed in specialized monofill sites, or disposed in the ground in an ash pit.

Sharp waste disposal: Even after decontamination, sharp waste may still pose physical risks. There may also be risk of reuse. Decontaminated sharp waste can be disposed of in safe sharp pits on the health-care facility premises or encapsulated by mixing waste with immobilizing material like cement before disposal. These procedures are only recommended in cases where the waste is handled manually and the landfill for general waste is not secured.

5.2.5 Occupational Health and Safety

Health and safety hazards in health facilities may affect healthcare providers, cleaning and other supporting staff personnel, and workers involved in waste management handling, treatment and disposal. Typical hazards which would be prevented with proper safety gear and practices include:

- Exposure to infections and diseases (blood-borne pathogens, and other potential infectious materials)
- Exposure to hazardous materials and or waste
- Fire safety

OSHA guideline for Laboratory Safety Guidance and WHO Laboratory biosafety manual are recommended to be used to minimize health hazards on the employees during operation of the proposed laboratories. OSHA Standards requires that employers "would furnish to each of his employees and a place of employment which are free from recognized hazards that are causing or likely to cause death or serious physical harm to his employees. The following OSHA for Laboratory Safety Guidance standards and WHO Laboratory biosafety manual must be respected to minimize such hazards.

The Occupational Exposure to Hazardous Chemicals in Laboratories standard The laboratory safety officer must be tailored to reflect the specific chemical hazards present in the laboratory where it is to be used. Laboratory personnel must receive training regarding the Laboratory standard, the CHP, and other laboratory safety practices, including exposure detection, physical and health hazards associated with chemicals, and protective measures.

The Hazard Communication standard: The standard requires evaluating the potential hazards of chemicals, and communicating information concerning those hazards and appropriate protective measures to employees. The standard includes provisions for: developing and maintaining a written hazard communication program for the workplace, including lists of hazardous chemicals present; labeling of containers of chemicals in the workplace, as well as of containers of chemicals being shipped to other workplaces; preparation and distribution of material safety data sheets (MSDSs) to workers and downstream employers; and development and implementation of worker training programs regarding hazards of chemicals and protective measures. This OSHA standard requires manufacturers and importers of hazardous chemicals to provide material safety data sheets to users of the chemicals describing potential hazards and other information. They must also attach hazard warning labels to containers of the chemicals. Employers must make MSDSs available to workers. They must also train their workers in the hazards caused by the chemicals workers are exposed to and the appropriate protective measures that must be used when handling the chemicals.

The Blood borne Pathogens standard requires employers to protect workers from infection with human blood borne pathogens in the workplace. The standard covers all workers with reasonably anticipated" exposure to blood or other potentially infectious materials (OPIM). It requires that information and training be provided before the worker begins work that may involve occupational

Exposure to blood borne pathogens, annually thereafter, and before a worker is offered hepatitis B vaccination. The Blood borne Pathogens standard also requires advance information and training for all workers in research laboratories who handle human immunodeficiency virus (HIV) or hepatitis B virus (HBV). The standard was issued as a performance standard, which means that the employer must develop a written exposure control plan (ECP) to provide a safe and healthy work environment, but is allowed some flexibility in accomplishing this goal. Among other things, the ECP requires employers to make an exposure determination, establish procedures for evaluating incidents, and determine a schedule for implementing the standard's requirements, including engineering and work practice controls. The standard also requires employers to provide and pay for appropriate PPE for workers with occupational exposures.

The Personal Protective Equipment (PPE) requires that employers provide and pay for PPE and ensure that it is used wherever "hazards of processes or environment, chemical hazards, radiological hazards, or mechanical irritants are encountered in a manner capable of causing injury or impairment in the function of any part of the body through absorption, inhalation or

physical contact in order to determine whether and what PPE is needed, the employer must "assess the workplace to determine if hazards are present, or are likely to be present, which necessitate the use of PPE. Based on that assessment, the employer must select appropriate PPE that will protect the affected worker from the hazard, communicate selection decisions to each affected worker and select PPE that properly fits each affected employee. Employers must provide training for workers who are required to use PPE that addresses when and what PPE is necessary, how to wear and care for PPE properly, and the limitations of PPE.

The Eye and Face Protection standard requires employers to ensure that each affected worker uses appropriate eye or face protection when exposed to eye or face hazards from flying particles, molten metal, liquid chemicals, acids or caustic liquids, chemical gases or vapors, or potentially injurious light radiation.

The Respiratory Protection standard requires that a respirator be provided to each worker when such equipment is necessary to protect the health of such individual. The employer must provide respirators that are appropriate and suitable for the purpose intended. The employer is responsible for establishing and maintaining a respiratory protection program that includes, but is not limited to, the following: selection of respirators for use in the workplace; medical evaluations of workers required to use respirators; fit testing for tight-fitting respirators; proper use of respirators during routine and emergency situations; procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing and discarding of respirators; procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators; training of workers in respiratory hazards that they may be exposed to during routine and emergency situations; training of workers in the proper donning and doffing of respirators, and any limitations on their use and maintenance; and regular evaluation of the effectiveness of the program.

The Hand Protection standard requires employers to select and ensure that workers use appropriate hand protection when their hands are exposed to hazards such as those from skin absorption of harmful substances; severe cuts or lacerations; severe abrasions; punctures; chemical burns; thermal burns; and harmful temperature extremes. Further, employers must base the selection of the appropriate hand protection on an evaluation of the performance characteristics of the hand protection relative to the task(s) to be performed, conditions present, duration of use, and the hazards and potential hazards identified.

The Control of Hazardous Energy standard (29 CFR 1910.147) establishes basic requirements for locking and/or tagging out equipment while installation, maintenance, testing, repair, or construction operations are in progress. The primary purpose of the standard is to protect workers from the unexpected energization or start up of machines or equipment, or release of stored energy. The procedures apply to the shutdown of all potential energy sources associated with machines or equipment, including pressures, flows of fluids and gases, electrical power, and radiation.

Safety Standards: These standards pertain to general industry, as well as laboratories. When laboratory workers are using large analyzers and other equipment, their potential exposure to electrical hazards associated with this equipment must be assessed by employers and appropriate precautions taken. Similarly, worker exposure to wet floors or spills and clutter can lead to slips/trips/falls and other possible injuries and employers must assure that these hazards are minimized. While large laboratory fires are rare, there is the potential for small bench-top fires, especially in laboratories using flammable solvents. It is the responsibility of employers to implement appropriate protective measures to assure the safety of workers.

5.2.6 Impact of None-routine Emergency Events

The existing hospitals and the laboratories that will be built by this project will need to have emergency response plan to contain accidents that may arise during none routine events. Such accidents may include fire out break or chemical spill. To minimize the non-routine emergency events the following guiding principles of response will have to be followed.

5.2.6.1 Emergency response plan for the containment of fire accident

• No open and unattended fires will be permitted.

• All hazardous materials are to be properly stored so as to avoid mixing of materials which could result in fires and/or explosions.

• Provide employees with firefighting training and ensure that firefighting equipment is provided or placed at appropriate place and ensure that all fire-fighting equipment are regularly maintained and serviced.

-The management of the laboratory would be certain of the presence of fire alarm and fire assembly hole and appropriate fire exit in the laboratory building Signage of fire hazard will be provided. Directions to exit in case of any fire incidence and emergency contact numbers would be provided. The emergency contact numbers would be displayed within the laboratory facility.

5.2.6.2 Emergency response plan for the containment of chemical spill

• All hazardous substances must be stored on an impervious surface in a designated area, able to contain 110% of the total volume of materials stored at any given time.

• Material safety data sheets (MSDS's) are to be clearly displayed for all hazardous materials.

• The integrity of the impervious surface and bunded area must be inspected regularly and any maintenance work conducted must be recorded in a maintenance report.

• Provide proper warning signage to make people aware of the activities within designated areas.

• Employees would be provided with absorbent spill kits and disposal containers to handle spillages. Train employees and contractors on the correct handling of spillages and precautionary measures that need to be implemented to minimize potential spillages.

• Employees would record and report any spillages to the responsible person.

• An Emergency Preparedness and Response Plan will be developed and implemented would and incident occur.

• Access to storage areas on site must be restricted to authorized employees only.

• Contractors will be held liable for any environmental damages caused by spillages.

5.2.7 Risk due to Laboratory biosafety issues

As no laboratory has complete control over the specimens it receives, laboratory workers may be exposed to organisms in higher risk groups than anticipated. To minimize such health risks, the proposed laboratories will be designated as bio-safety level 2. For the proposed laboratories to be designated as BSL 2, the following standards practices indicated in the WHO Bio-safety Laboratory Manual of 2004 will have to be respected in order to mitigate the bio-safety risk during the laboratories operation.

5.2.7.1 Code of practice

Each laboratory would adopt a safety or operations manual that identifies known and potential hazards, and specifies practices and procedures to eliminate or minimize such hazards. Specialized laboratory equipment is a supplement to but can never replace appropriate procedures. The most important concepts are listed below.

Access

- The international biohazard warning symbol and sign must be displayed on the doors of the rooms where microorganisms of Risk Group 2 or higher risk groups are handled;
- Only authorized persons would be allowed to enter the laboratory working areas;

- Laboratory doors would be kept closed;
- Children would not be authorized or allowed to enter laboratory working areas;
- Access to animal houses would be specially authorized;
- No animals would be admitted other than those involved in the work of the laboratory.

Personal protection

- Laboratory coveralls, gowns or uniforms must be worn at all times for work in the laboratory.
- Appropriate gloves must be worn for all procedures that may involve direct or accidental contact with blood, body fluids and other potentially infectious materials or infected animals. After use, gloves would be removed aseptically and hands must then be washed;
- Personnel must wash their hands after handling infectious materials and animals, and before they leave the laboratory working areas;
- Safety glasses, face shields (visors) or other protective devices must be worn when it is necessary to protect the eyes and face from splashes, impacting objects and sources of artificial ultraviolet radiation;
- It is prohibited to wear protective laboratory clothing outside the laboratory, e.g. in canteens, coffee rooms, offices, libraries, staff rooms and toilets;
- Open-toed footwear must not be worn in laboratories;
- Eating, drinking, smoking, applying cosmetics and handling contact lenses is prohibited in the laboratory working areas;
- Storing human foods or drinks anywhere in the laboratory working areas is prohibited;
- Protective laboratory clothing that has been used in the laboratory must not be stored in the same lockers or cupboards as street clothing.

5.2.7.2 Procedures

- Pipetting by mouth must be strictly forbidden;
- Materials must not be placed in the mouth. Labels must not be licked;
- All technical procedures would be performed in a way that minimizes the formation of aerosols and droplets;
- The use of hypodermic needles and syringes would be limited. They must not be used as substitutes for pipetting devices or for any purpose other than parenteral injection or aspiration of fluids from laboratory animals;

- All spills, accidents and overt or potential exposures to infectious materials must be reported to the laboratory supervisor. A written record of such accidents and incidents would be maintained;
- A written procedure for the clean-up of all spills must be developed and followed.
- Contaminated liquids must be decontaminated (chemically or physically) before discharge to the sanitary sewer. An effluent treatment system may be required, depending on the risk assessment for the agent(s) being handled;
- Written documents that are expected to be removed from the laboratory need to be protected from contamination while in the laboratory.

5.2.7.3 Laboratory working areas

- The laboratory would be kept neat, clean and free of materials that are not pertinent to the work;
- Work surfaces must be decontaminated after any spill of potentially dangerous material and at the end of the working day;
- All contaminated materials, specimens and cultures must be decontaminated before disposal or cleaning for reuse;
- Packing and transportation must follow applicable national and/or international regulations;
- When windows can be opened, they would be fitted with arthropod-proof screens.

5.2.7.4 Bio-safety management

- It is the responsibility of the laboratory director (the person who has immediate responsibility for the laboratory) to ensure the development and adoption of a bio-safety management plan and a safety or operations manual;
- The laboratory supervisor (reporting to the laboratory director) would ensure that regular training in laboratory safety is provided;
- Personnel would be advised of special hazards, and required to read the safety or operations manual and follow standard practices and procedures. The laboratory supervisor would make sure that all personnel understand these. A copy of the safety or operations manual would be available in the laboratory;
- There would be an arthropod and rodent control programme;

Appropriate medical evaluation, surveillance and treatment would be provided for all personnel in case of need, and adequate medical records would be maintained.

5.2.7.5 Health and medical surveillance

The medical director of the hospitals through the laboratory director is responsible for ensuring that there is adequate surveillance of the health of laboratory personnel. The objective of such surveillance is to monitor for occupationally acquired diseases. Appropriate activities to achieve these objectives are:

- Provision of active or passive immunization;
- Facilitation of the early detection of laboratory-acquired infections;
- Exclusion of highly susceptible individuals (e.g. pregnant women or immune-compromised individuals) from highly hazardous laboratory work;
- Provision of effective personal protective equipment and procedures;

5.2.7.6 Guidelines for the surveillance of laboratory workers handling microorganisms at Bio-safety Level 2

- A pre-employment or pre-placement health check is necessary. The person's medical history would be recorded and a targeted occupational health assessment performed;
- Records of illness and absence would be kept by the laboratory management;
- Women of childbearing age would be made aware of the risk to an unborn child of occupational exposure to certain microorganisms, e.g. rubella virus. The precise steps taken to protect the foetus will vary, depending on the microorganisms to which the women may be exposed;

For this reason, continuous in-service training in safety measures is essential. An effective safety programme begins with the laboratory managers, who would ensure that safe laboratory practices and procedures are integrated into the basic training of employees. Training in safety measures would be an integral part of new employees' introduction to the laboratory. Employees would be introduced to the code of practice and to local guidelines, including the safety or operations manual. Measures to assure that employees have read and understood the guidelines, such as signature pages, would be adopted. Laboratory supervisors play the key role in training their immediate staff in good laboratory techniques. The bio-safety officer can assist in training and with the development of training aids and documentation.

Staff training would always include information on safe methods for highly hazardous procedures that are commonly encountered by all laboratory personnel and which involve:

- Inhalation risks (i.e. aerosol production) when using loops, streaking agar plates, pipetting, making smears, opening cultures, taking blood/serum samples, centrifuging, etc.

- Ingestion risks when handling specimens, smears and cultures;
- Risks of per-cutaneous exposures when using syringes and needles;
- Bites and scratches when handling animals;
- Handling of blood and other potentially hazardous pathological materials
- Decontamination and disposal of infectious material;

5.2.8 Community Health and Safety

The guidelines recommend implementation of risk management strategies to protect general community from biological, physical, chemical, or other hazards associated with the laboratories operation phase. Key areas to consider are:

- **General site hazards:** where the laboratory activities can affect people due to the contaminated materials and hazardous chemical waste generated from the laboratories.
- **Disease Prevention:** ensuring that risk of disease from laboratory related activities such specimens processing and infectious waste generated from the laboratories.

WBG EHS Guidelines for Community Health and Safety is recommended to be used to minimize health hazards during operation of the proposed laboratories as follow:

- Providing surveillance and active screening and treatment of workers
- Preventing illness among workers in local communities by:
  - Undertaking health awareness and education initiatives, for example, by implementing an information strategy to reinforce person-to-person counseling addressing systemic factors that can influence individual behavior as well as promoting individual protection, and protecting others from infection, by encouraging condom use
  - Training health workers in disease treatment
  - Conducting immunization programs for workers in local communities to improve health and guard against infection
  - Providing health services
- Providing treatment through standard case management in on-site or community health care facilities. Ensuring ready access to medical treatment, confidentiality and appropriate care, particularly with respect to migrant workers
- Promoting collaboration with local authorities to enhance access of workers families and the community to public health services and promote immunization

5.2.9 Impacts during decommissioning

Decommissioning entails closure of the auxiliary facilities and services such as quarry mines, construction materials storage facilities, leftover materials (sand, cement, iron bars etc..). Decommissioning impacts for a project of this nature are likely to be minor, localised and short term.

To minimize impacts of the decommissioning activities it important to prepare environmentally management plan that will guide the contractor on how to safely demolish the laboratory building and facilities to safely dispose demolished wastes. According to this plan the contractor at the time of demolishing and dismantling the laboratory facilities is expected fenced the site to prevent the site from being accessed by human and animals.

5.3 Generic Environmental and Social Management Framework (ESMF)

Environmental and social impact mitigation for the Ethiopian Infectious Diseases Control System Enhancement Project that promote African Public Health Laboratory Networking Systems reflects generic mitigation measures that will minimize the adverse environmental and social impacts emanating from activities during preconstruction, construction, operation, decommissioning phases of the project.. These measures provided in the Environmental Social Management Framework (ESMF) indicated in Table 4, includes broad measures to manage laboratory wastes management. The purpose of the ESMP is to safeguard environmental and social impacts are mitigated. ESMP will basically consist of the following:

- Potential environmental impacts;
- Mitigation/enhancement measures against each impact;
- Responsible institutions to carry out the mitigation measures;
- Timeline for the implementation of the mitigation measures

ESMP for the individual laboratory projects (Sub-Projects) will be prepared by modifying the ESMF of the ACRIFP taking into consideration specific sub-project activities on the specific sites. Activities and impacts relating to Laboratory Waste Management would be based on the Laboratory and Health- Care Waste Management Plans from which key elements to be managed and monitored would be drawn up and included in the ESMP.

Table 4: Generic Environmental and Social Management Framework

Impact	Mitigation Measures	Responsible Institution
During Construction Phase		
Laboratory Design fault	During laboratory design consider the standard requirements indicated in WBG EHS guideline, OSH laboratory safety guidance and WHO laboratory bio-safety manual 3rd Edition which includes: • Adequate spaces for woks and staff • Infectious diseases and occupational health hazards prevention and control systems • Emergency management systems • Waste disposal systems	MOH/EPHI/ Contractor
Impact on the laboratory staff and on patients-	Construction activities will create risks to patients and staff and may also adversely impact on the existing laboratory diagnosis affecting the day to day operation of the hospital	Contractor
Impact on Landscape	Piles of construction wastes and packaging materials may affect the scenery of the hospital and also restrict peoples' movement within the premises of the hospital.	
Soil erosion due to clearance of vegetation and movement of heavy construction machineries.	Implement appropriate methods as recommended in the WBG EHS guideline-sub section 4.1. - Reducing or preventing erosion by: contouring and minimizing length and steepness of slopes, mulching to stabilize exposed areas, re-vegetating areas promptly, -Limit extent of vegetation clearing on construction sites, materials mining sites, working areas and service roads -Control movement of vehicles; Light construction machinery would be used and excavation would be strictly carried out within the space provided in the layout -Regular use of water sprays and compacting soil on earth roads and around working areas - Re-plant trees and vegetation after construction	Regional Health Bureau/ Contractor
Soil contamination from cement, paints, lubricants, and fuels	Fuel and lubricants would be carefully collected and disposed in an environmentally safer way at the site designated for this purpose; Contain construction wastes on lined surfaces and dispose wastes in a pit prepared for this purpose.	contractors
Water pollution From construction wastes as well as on-site make shift toilets	- Collect and dispose wastes in designated disposal sites as required by the Local Authority -Provide appropriate and approved temporary toilets	Contractors

Impact	Mitigation Measures	Responsible Institution
-Change in natural drainage flow pattern and surface water runoff -Drainage clogging from rubble, cement, paints, lubricants and fuels as well as makeshift toilets	Use WBG EHS guideline recommendation for the septic systems -Collect and dispose wastes in designated disposal sites as required by the Local Authority - Keep all drains clear of silt and debris regularly and after construction	Contractors
Temporary loss of access to services such as water telephones and electricity due to possible damage by contractor	Identify and divert locations water pipes, telephone and electric cables before construction and relocate laboratory equipment's to a room reasonably away from construction activities	Contractor /Woreda Health Office
Spread of HIV and other contagious diseases due to human contact among the construction work force.	Distribute condoms and Create awareness on the transmission mechanisms of these diseases	Contractor /Woreda Health Office
Intensification of Malaria	-Prevention of larval and adult propagation through sanitary improvements and elimination of breeding habitats close to human settlements.	Contractor /Woreda Health Office
Air pollution due to emissions from construction machinery and from dust	- Applying Dust suppression techniques as recommended in WBG EHS guideline -Water would be sprayed on access roads and construction sites and loose soil would be compacted and construction machinery would be regularly maintained as recommended by dealers	Contractor
Noise & vibration disturbances due to movement of heavy plant and equipment	- Planning activities in consultation with local communities - Construction activities during night time would be avoided.	Contractor
Temporary obstruction of walkways due to road and sidewalk barriers	Provide alternative routes and passages with adequate and appropriate directional signs	Contractor
Traffic accident due to moving machinery	Planning and segregating the location of vehicle traffic, machine operation, and walking areas, and controlling vehicle traffic through the use of one-way traffic routes, establishment of speed limits, and on-site trained flag people wearing high-visibility vests or outer clothing covering to direct traffic	contractor

Impact	Mitigation Measures	Responsible Institution
During Operation Phase		
Occupational health and safety risks on health care providers and supportive staff due to improper work procedures and healthcare waste management	-Provide personal Protection equipment - Implement engineering control systems like primary and secondary barriers - Organize and implement medical surveillance which includes medical service and immunization programs - Provide health and safety training - Adopting and implementing safety manuals aligned with OSH guideline and WHO laboratory biosafety manual. - develop and implement safety standards.	Administration of the respective laboratory
improper laboratory waste management can lead water and soil contamination	- Provide colour coded waste bins for the different types of waste generated	Administration of the respective laboratory
	Develop and implement appropriate plan, strategies and action plan for waste minimization and segregation	Regional Health Bureau/ Administration of the respective hospitals
	-Use appropriate facilities and methods as stipulated in the WBG EHI guideline to collect, and transport wastes, treat and dispose them using appropriate technologies and disposal facilities such as incineration, autoclave and sanitary landfill	
	Laboratory staff s and supportive staffs would be trained on waste management and handling during operation.	
	Laboratory would have standard operation and decontamination procedure manuals and clearly displayed at appropriate point (s) with the laboratory	
	- Use WBG EHS guideline recommendations for the septic systems - Use appropriate waste drainage system leading to septic tank or public sewerage facilities or treatment technologies such as activated sludge and sanitary facilities, if available the town municipality	Administration of the respective laboratory
	-Use contingency containment facilities to collect accidental health care waste spillage - Training workers on the correct transfer and handling of fuels and chemicals and the response to spills Provide emergency materials like chemical and biological spill kits and MSDS.	Regional Health Bureau/ Administration of the respective hospitals
	-Proper selection of disposal sites -Adhering to recommended waste disposal practices (i.e. WBG EHS guideline)	Regional health Bureaus/Regional EFCCC
Air pollution from aerosol generated activities , health care waste incineration and volatile chemicals	- Ensure proper handling of specimen and laboratory waste by personnel as recommended in WHO biosafety Manual. - Ensure adequate ventilation in laboratories and treatment areas	Administration of the respective laboratory

Impact	Mitigation Measures	Responsible Institution
	Use appropriate efficient incinerator to treat health care wastes containing organic compounds	Administration of the respective laboratory
Environmental pollution and community health risks due to improper waste disposal and specimen handling and transportation.	- Adhere to good microbiological techniques as recommended in WHO Biosafety Manual - Provide appropriate protective clothing to all staff throughout the waste management chain to prevent infection - Establish recommended laboratory specimen collection and transportation systems as recommended in the HCWMP/LWMP -Conduct civic health education to patients and the general public -Dispose HCW and LW in designated places, following approved disposal methods, as recommended in the HCWMP/LWMP -Secure all waste throughout the waste management chain and provide adequate security to prevent scavenging	Administration of the respective laboratory
	Develop and implement risk management strategies for biological, physical, and chemical releases during laboratory operation that aligned with WBG EHS Guidelines for Community Health and Sa	Administration of the respective laboratory
	Minimize risk by meeting the requirements indicating in the bio-safety manual of WHO explained above.	MOH/EPHI/ regional health Bureau
	Adhering to WBG EHS Guideline recommendations for Facility Design: -Ventilation systems that provide isolation and protection from airborne infections; provide adequate potable water supplies of to reduce risks of exposure Provision of hazardous material and waste storage and handling areas; Develop and implement chemical hygiene plan	Contractor
Potential risks associated with BSL 2 Laboratories operation	• Implement the facility containment devices, and administrative controls BSL-2 • Good Microbiological Practices for the BSL 2 Laboratories • Special Practices for BSL 2 laboratories • Use Personal Protective Equipment during performing activities in BSL 2 Laboratories • Use laboratory Secondary Barriers for BSL2 laboratories	Regional Health Bureau/Administration of the respective laboratories

Impact	Mitigation Measures	Responsible Institution
escaping of infectious agents from BSL-2 laboratories	• Provide training on handling infectious agents and waste handling, transportation, and storage • Maintain and calibrate all equipment periodically • Provide vaccines or therapeutic measures for all risks • Sterilize all equipment by autoclave or chemical disinfection • Establish biosecurity system place	Regional Health Bureau/Administration of the respective laboratories
Lack of Emergency management systems can cause fire, devastation, injury and death	-Develop and implement emergency management plans. -Regular drills would constantly follow on various possible incidences. This will test the response of the involved stakeholders. Such drills will keep them alert and they will become more responsive to in the case of incidences. -Use signage to warn staff and/ or visitors that are not involved in laboratory work of dangerous places. -Develop evacuation procedures to handle emergency situations. -Provide emergency materials like first aid kits, chemical and biological spill kits, emergency shower and eye wash, fire controlling systems, -Develop and implement emergency reporting systems -Develop and implement Medical insurance and compensation -Develop and implement chemical management plan.	Regional Health Bureau/Administration of the respective laboratories
During Decommissioning Phase		
Creation of stagnant water pools at the lower spot of the dismantled laboratory buildings during commissioning creates favorable condition for mosquito breeding	Fill back lower spots that may creation stagnant water and apply the WBG EHS recommended techniques for control of malaria and / other vectors	Contractor
Surface water siltation from backfilling and restoration activities	Use water sprays on roads and working sites and compact loose soils.	Contractor
Cumulative Impact due to Healthcare Waste	Existing institutions that are releasing health care wastes would treat their waste by using high temperature incinerator of higher efficiency to minimize cumulative impact.	Regional Health Bureau

Impact	Mitigation Measures	Responsible Institution
Impact on workers safety	-Provide appropriate protective clothing to the work force engaged in dismantling the laboratory buildings and ensure they use this equipment during project decommissioning - prepare environmentally management plan that will guide the contractor on how to safely demolish the laboratory building and facilities to safely dispose demolished wastes.	Contractor

Note:

- Table above would be considered as the main frame to guide preparation of social and environmental Management Plans of the laboratory projects (Sub-project) taking into consideration activities and the sites specific to the sub-project.
- Since the ESMF is generic framework and not site specific, it will not be accurate to include cost of the proposed mitigation measures in the in the ESMF table indicated above. The cost of the proposed mitigation measures will be estimated at the time of the preparation of the ESIA/ESMP of specific sub projects at different locations of the regional states
- Specific medical wastes management approach will be assessed when ESIA/ESMP for each BSL 2 laboratory is prepared based on site-specific conditions.

6. ESMF Implementation and Monitoring Process

6.1 Sub-project Screening and Approval Process

The objective of screening sub projects is to assess any potential safeguard issues early in the design and preparation process and classify the sub-projects either as B or C, depending on the level, and scope of potential environmental and social impacts. The screening of ACRIFP subprojects will be done by completing screening checklist tables indicated in annex 1.

Step 1: Sub-project Identification

The initial step will be sub-project or business plan identification. Sub-projects and business plans will be identified by the client. In this particular project, the Ministry of Health has already identified the sub-projects and specific sites of these sub-projects have already been decided.

Step 2: Checking Eligibility of subprojects

At this stage the sub-projects will be subjected to screening process by the Ethiopian Public Health Institute (EPHI) against environmental and social checklist indicated to check their eligibility for ACRIFP financing.

In checking the eligibility of the sub projects the questions in annex 3 would be answered as “Yes” or “No”. If the answer to any one of the questions in the annex is ‘Yes’, then the subproject will be redesigned to be acceptable or stopped if redesigning is not possible. If on the contrary the answer is ‘No’ for all the above questions, then one must proceed to the next step. This will be applicable for screening the 15 new labs and 8 existing labs.

Step 3: Environmental and Social Screening

At this stage the subprojects will be screened and approved by the safeguard experts of EPHI and will be approved by the Environment, Forest and Climate Change Commission and the World Bank using Environmental and Social Screening Checklist of these institutions. If the sub-project has high or medium environmental and social concerns, the EPHI would ensure that all the necessary mitigation measures are incorporated in the ESIA report before approval.

Furthermore, EPHI safeguard experts would assess the significance of potential impacts using environmental and social impact rating checklist provided under annex 4. This will be applicable for screening the 15 new labs and 8 existing labs. The checklist must be filled, and

number of potential impacts marked as None, Low, Medium, High and Unknown and will be used to determine individual and the overall impact rating of the sub-project. The table 5 below is a guidance to determine what action would be taken before proceeding to the next level based on the results.

Table 5: Rating and classification of potential impacts of Sub-projects

For sub-projects with no impact (All impact rating becomes 'None')	These types of subprojects would be labeled as '**subprojects of no environmental and social concern'.** These types of sub-project without further delay has to be approved and cleared by Woreda or Regional office responsible for environment
For sub-projects with low, medium and/or one high impact	These types of subprojects would be labeled as '**Sub-projects of medium environmental and social concern'.** In this case, **i**ncorporate potential mitigation measures into the design of the subprojects would be integrated and ESMP would be prepared.
Subprojects cause more than one high potential impact plus more than two unknown impacts	These types of subprojects would be labeled as '**subprojects of high environmental and social concern'.**. In this case, ESMP would be prepared and/or conducting additional ESIA assessment may also be required.
Subprojects where it is difficult to predict the potential impacts, i.e., subprojects which have two or more unknown potential impacts	These types of subprojects would be labeled as '**subprojects of unknown environmental and concern**' because of the many unpredictable potential impacts. In this case, ESMP would be prepared and/or additional assessment will be required

For sub-projects labelled as 'unknown' and/or 'high' environmental and social concern, the need to conduct additional assessment would be decided through discussion among federal and regional safeguard specialists. The discussion and final decision would be compatible with the EIA guideline, 2000 and the World Bank OP/BP 4.01.

Step 4: ESIA/ESMP preparation, including consultation and disclosure.

The Regional Health bureaus will work closely with Regional Environment, Forest and Climate Change Agencies to assist them in identification appropriate safeguards tools and in review and approval of the safeguards tools to be prepared for the for the 15 new labs and 8 existing labs. If Regional Environment, Forest and Climate Change Agencies advises that the subprojects (any the 15 new labs and 8 existing labs) do not require full ESIA, an environmental and social management plan will be prepared. If a full ESIA is required per the recommendation of the

Regional Environment, Forest and Climate Change Agencies, the ESIA should be conducted based on the TOR for ESIA. The TOR for ESIA should also be submitted to the World Bank country office for final review and no objection. The ToR will also give details of the composition of the ESIA team (including their experience and field of expertise) and timelines. The ESIA report will include but not limited to;

- Project Description: A description of key components of the proposed project, the implementing agents, a brief history of the project and its justification;
- Baseline environmental information comprising physical, biological and socioeconomic conditions of the site to be assembled and evaluated;
- A description of the pertinent legislation, regulations and standards, as well as environmental policies applicable to the proposed project and the appropriate authority jurisdictions;
- Identification of impacts related to project elements and an analysis of severity and duration of impacts;
- Prescription of mitigation measures and development of an environmental management plan to neutralize the effects of negative impacts
- Development of a monitoring plan to ensure that the proposed mitigation measures are implemented, and the desired remediation effects achieved;
- Public consultation and documentation of stakeholder views. It is mandatory for the ESIA study to undertake public consultation with all stakeholders in the project's area of influence.

The completed ESIA report will then be submitted to Regional Environment, Forest and Climate Change Agencies for clearance with an official application for review and approval. The ESIA should also be reviewed and cleared by the World Bank before disclosure. Regional Environment, Forest and Climate Change Agencies will review the full or partial ESIAs and ESMPs submitted to it by the implementing institution. The purpose of review is to examine and determine whether the full/partial ESIA and EMP are adequate assessment of the environmental and social impacts of the subproject under consideration, and enough mitigation measures have been provided for the negative impacts.

The Regional Environment, Forest and Climate Change Agencies will review within 15 days the ESIA and may decide to:

a. Accept the document - with conditions relating to implementation;

b. Accept the documents with required and/or recommended amendments; or

c. Reject the document with comments as to what is required to submit an acceptable ESIA and ESMP.

If a full ESIA is not required, Regional Environment, Forest and Climate Change Agencies will provide the Project Coordination Unit/ the beneficiary health facilities/ the regional environmental and social safeguards focal person in connection to preparation of an ESMP/partial ESIA. The beneficiary health facilities/regional bureaus will then prepare and submit the ESMP (which will be based on generic E&S management and monitoring plan included in this ESMF) to Environmental Protection Authority for review and clearance. Environmental Protection Authority review and clear the ESMP as soon as possible to minimize implementation delay. Before equipping the 8 existing regional labs, an environmental and social audit will be conducted based on Annex 7 and 8.

Consultation and Disclosure of Subprojects Information

Before the approval of the subprojects, the project implementing unit should properly consult the stakeholders and make ESMP and or ESIA available for public review at a place accessible to local people and in a form, manner and language they can understand. The public will be invited to comment on these reports prior to their approval. The public should also participate and be consulted at all levels of environmental and social assessments including eligibility checks, screening, scoping, impact identification and rating.

Step 5: Subproject ESMP implementation, monitoring, supervision and reporting.

The client will ensure that an appropriate environmental and social safeguards compliance monitoring and reporting system will be established. The goals of implementation monitoring are to:

- measure the success rate of the project;
- verify the accuracy of the environmental and social impact predictions;
- determine the effectiveness of measures to mitigate adverse effects of projects on the environment;
- determine whether interventions have resulted in dealing with negative impacts; determine whether further interventions are needed, or monitoring is to be extended in

A guideline Monitoring and Evaluation of the Implementation of ESMF annexed (Annex 5)

6.2 ESMF Implementation Arrangement

6.2.1 Institutional Arrangements

One of the main purposes of the ESMF is to establish roles and responsibility of the institutions and stakeholders to successfully implement the project considering the environmental dimensions (table 6).

6.2.2 Public Health Infrastructure Directorate (PHID)

The PHID at the Federal Ministry of Health (FMOH) would serve as the implementing body with the mandate to:

- Prepare plans for effective project development and management;
- Co-ordinate the project programs and actions plans, and develop the various sub-project activities;;
- Manages ACRIFP project construction contracts and supervision of project construction;
- Ensure that the design of all ACRIFP laboratories incorporate provision for addressing environmental issues including facilities for infectious and hazardous healthcare waste management
- Develop environment, health and safety standards for contractors; incorporate such requirements in ACRIFP laboratory construction contracts, and monitoring compliance to these requirements;

6.2.3 Environmental and Social Safeguards committee

To ensure sustainability in all project activities, an environmental and social development safeguards committee would be formed at EPHI that reports directly to the PHID and members of the committee will be EPHI, PHID and representative of regional health bureau who delegated as project focal persons. The objective of the environmental/social safeguards committee is to ensure the effective management of environmental and social concerns in all aspects of the project.

The roles and responsibilities of the Environmental and Social safeguard committee include:

- Review all environmental and social safeguard documents prepared by environmental and social consultants and ensure adequacy under the World Bank Safeguard Policies;
- Co-ordinate application, follow up processing and obtain requisite clearances required for the project;

- Establish dialogue with stakeholders and community groups to ensure environmental and social concerns are addressed and incorporated and implemented in the project

Table 6: Implementation arrangement and Roles and Responsibilities institute of the ESMF

S. No	Institute	Roles and Responsibilities
1	MOH/PHID (the Project implementation unit at Federal Level)	• Assign environmental and social focal person at the Federal project implementation unit) • Arrange training on environmental and social framework to the environmental and social safeguards focal persons. • Write a periodic safeguards compliance report to the Bank • Compliance with World Bank Safeguards Policies and other relevant laws in Ethiopia in line with this ESMF • Efficient implementation of ACRIFP project
2	Environmental and Social Safeguards committee	• Assists PHID to comply with and fully implement World Bank Safeguards Policies and other relevant laws in Ethiopia. • Take lead in ensuring adequate screening and scoping of project for the appropriate safeguard instrument. • Review all safeguard reports before it is sent to the World Bank
3	Federal Ministry of Health, Regional Health Bureaus	• Assign safeguards focal person who will be responsible for compliance with the requirement of the ESMF • Organize training on the ESMF of the project to safeguards focal persons who will be responsible for safeguards issues • Make sure that screening and preparation of ESIA/ESMP done as per the requirements of the Project • Allocate budget for capacity building and risk mitigation measures • Organize environmental health, hygiene, sanitation and public health services and the management of solid, liquid and hazardous waste.
4	Health Facilities where the BSL2 labs will be constructed or equipped	• Assign an environmental and social safeguards focal person • Facilitate the preparation of site-specific safeguards tools (ESMP or ESIA as deemed necessary) • Write periodic reports on safeguards compliance to the Regional Environmental and social safeguards focal person • Ensure that environmental and social risk mitigation measures are properly taken
5	Environment, Forest and Climate Change Commission (EFCCC and regional EFCCC	• Enforcing and ensuring compliance to the ESIA proclamation which currently is being implemented through delegated authority, • Reviewing ESMF's and monitoring the implementation of ESMF recommendations which is also in part being implemented through delegated authority, • Regulating environmental compliance and developing legal instruments that ensure the protection of the environment,

		• Ensuring that environmental concerns are mainstreamed into sector activities, • Coordinating, advising, assessing, monitoring and reporting on environment-related aspects and activities.

6.3 ESMF Monitoring, Supervision and Reporting

Environmental and social monitoring needs to be carried out during the construction as well as operation and maintenance of the sub-projects to ensure that mitigation measures are implemented, have the intended result, and that remedial measures are undertaken, if mitigation measures are inadequate or the impacts have been underestimated within the environmental and social Assessment (Table 7).

At the Federal Project implementation unit, an environmental and social safeguards focal person will be assigned who, in coordination with the regional level focal person, will be responsible for overseeing safeguards compliance during construction and operation of the BSL2 labs. At Regional level, an environmental and social safeguard focal person will be assigned by the health bureau who will be responsible for monitoring and reporting on the preparation and implementation of ESMP and ESIA throughout the sub-project duration. S/He will supervise and review environmental and social safeguard compliance. S/He will specifically be monitoring of the following aspects:

- The environmental and social assessment processes (screening; ESMP/ESIA preparation);
- Check approval of screening reports and safeguards tools (ESMP/ESIA) as appropriate by the environmental protection authority
- The monitoring of the implementation of the mitigation measures;
- Monitoring of environmental and social issues and the supervision of the contractor civil works during the construction process;
- Monitoring of environmental and social issues during operations and maintenance using the environmental indicators indicated in the ESMF;
- Supervision of the implementation of the ESMF
- Submission of monitoring reports to the Federal Project Coordination Unit

At the operational level, each beneficiary health facility will delegate a focal person who will be responsible for:

- subproject screening and facilitating the approval the screening report by Environmental protection authority
- preparation of ESMP and facilitating the approval of the ESMP by environmental protection authority
- make sure deployment of a consultant with an appropriate team mix for ESIA if an ESIA should be conducted, seek approval the ESIA by the environmental protection authority,
- supervise the implementation of mitigation measures
- write periodic reports

Quarterly and annual environmental and social safeguard performance reports should be prepared at Beneficiary Health Facility, regional Health Bureau and federal Project Coordination Unit levels. At a Beneficiary Health Facility level, quarterly and annual report will be prepared by the environmental and social safeguards focal person in the Health Facility. The objective of the report should provide clear information about the activities carried out so as to the environmental and social safeguards requirements of the project. This report will be submitted to regional environmental and safeguards focal person. The regional focal person shall compile and analyse the reports from the focal persons at each beneficiary health facility and will submit it to the federal project coordination unit. At the federal level, the quarterly and annual report will be prepared by environmental and social safeguard specialist federal project coordination unit and will be submitted to the World Bank country office.

Besides, annual reviews of implementation of the ESMF will be conducted. The annual reviews are intended improve procedures and capacity for safeguards compliance Annual reviews should be undertaken after the annual ESMF report has been prepared and before Bank supervision of the Project, at the closing of each year of the project.

Table 7: Table Generic Environmental and Social Monitoring Plan of the proposed Project

Project Stage/ Components	Impacts	Mitigation Measures	Monitoring Indicator	Frequency of monitoring per site	Institution to Monitor
During Construction					
Design	Laboratory Design fault	During laboratory design planning consider the standard requirements indicated in WBG EHS guideline, OSH laboratory safety guidance and WHO laboratory bio-safety manual 3rd Edition which includes: • Adequate spaces for woks and staff • Infectious diseases and occupational health hazards prevention and control systems • Emergency management systems • Waste disposal systems	approved design against WBG EHS guideline, OSH laboratory safety guidance and WHO laboratory bio-safety manual,	once	MOH/EPHI/Contractor
Overall impact management	All impacts	Preparation of Simple environmental and social mitigation Measures	Approved Environmental management plan	Once to approve Environmental management plan	FECCC
Soil	Soil Erosion due to steepness of slopes and destruction of trees and vegetation	-Reducing erosion by: contouring and minimizing length and steepness of slopes, mulching,	-Presence of erosion control methods	Twice / Initially	Contractors/ Woreda FECC Office
		- Limit extent of construction space and vegetation Clearing/Re-vegetating areas promptly	-Number of trees cleared during construction compared to the trees planted to compensate losses	Twice during site clearing and percentage of actual built up area	Woreda FECC Office
	Soil contamination	Contain construction wastes on lined surfaces and dispose wastes in a pit prepared for this purpose.	-Presence of appropriate (lined & covered areas)	Monthly	Woreda FECC Office & Health Office
Water Pollution	Water pollution from construction wastes as well as on-site make shift toilets	Collect and dispose wastes in designated disposal sites as required by the Local Authority Provide appropriate	-Number of times waste is collected and disposed of on designated sites	Monthly	Environmental Woreda FECC Office & Health Office

Project Stage/ Components	Impacts	Mitigation Measures	Monitoring Indicator	Frequency of monitoring per site	Institution to Monitor
		and approved temporary toilets	-Number of temporary toilets		
	Temporary loss of access to services such as water telephones and electricity	Identify and divert locations water pipes, telephone and electric cables before construction and	Number of service facilities identified and diverted	Once/ initially	Woreda Administration
Air pollution	-Air pollution due to emissions from construction machinery and from dust	- Applying Dust suppression techniques as recommended in WBG EHS guideline -Water would be sprayed on access roads and construction sites and loose soil would be compacted	- Observation of method adherence to WBG EHS guideline -Total area sprayed with water and compacted	-Monthly -Monthly	Woreda FECC Office & Health Office
Noise & vibration	Noise & vibration disturbances due to movement of heavy plant and equipment	- Planning activities in consultation with local communities - Perform construction and maintenance works during official government working hours	Number of complaints against noise and vibration due to operation during un-authorized working hours	-Monthly	Woreda FECC Office
Health	Impact on hospital staff and on patients	-construction machineries would have silencer that minimize noise reaching the hospital workers and patients	Check hearing ability of patients and workers	Every month	Woreda health office
Traffic accident	Traffic accident due to moving machinery	Segregating the location of vehicle traffic, machine operation, and walking areas, and controlling vehicle traffic through the of one-way traffic routes, establishment of speed limits,	-Presence of appropriate sigh in appropriate location	-Monthly	Woreda FECC Office & Health Office
Landscape	Temporary obstruction of walkways due to road and sidewalk barriers	Provide alternative routes and passages with adequate and appropriate directional signs	Presence of standardized signs to ensure free and safe passage	-Quarterly	Woreda FECC Office & Health Office
Health and social	Spread of TB, STIs, HIV and Aids	Distribute condoms and Create awareness on the transmission mechanisms of these diseases	-Number of awareness meetings conducted -Number of condoms distributed	Monthly during Construction period	Woreda Health Office
	Malaria intensification	Implementation of integrated vector control	Prescience of integrated	Quarterly	Woreda Health

Project Stage/ Components	Impacts	Mitigation Measures	Monitoring Indicator	Frequency of monitoring per site	Institution to Monitor
		programs	vector control programs		Officer
During Operation					
Water and Soil contamination from Waste spillage	improper laboratory waste management can lead water and soil contamination	- Use WBG EHS guideline recommendations for the septic systems	-Presence of drainage line properly connect to a functioning septic tank or public drainage	-Quarterly	Woreda FECC Office & Health Office
		- Use appropriate waste drainage system leading to septic tank/public sewerage facilities /treatment technologies such as activated sludge and sanitary facilities, if available the town municipality	- Presence of appropriate treatment technologies adhering to WBG EHS guideline	Quarterly	Woreda FECC Office & Health Office
		Develop and implement appropriate plan, strategies and action plan for waste minimization and segregation	Presence of approved plan, strategies and action plan Presence of performance audit records	-Quarterly	Woreda FECC Office & Health Office
		Laboratory staff s and supportive staffs would be trained on waste management and handling during operation.	Number of staffs trained on HCWM.	-Quarterly	Woreda FECC Office & Health Office
		Laboratory would have standard operation and decontamination procedure manuals and clearly displayed at appropriate point (s) with the laboratory	Presence of approved SOP or manuals	-Quarterly	Woreda FECC Office & Health Office
		-Proper selection of disposal sites -Adhering to recommended waste disposal practices (i.e. WBG EHS guideline)	Observation of appropriate waste disposal designated sites	-Quarterly	Woreda FECC Office & Health Office

Project Stage/ Components	Impacts	Mitigation Measures	Monitoring Indicator	Frequency of monitoring per site	Institution to Monitor
		-Use contingency containment facilities to collect accidental health care waste spillage	- Presence of standard procedures for spill control	- Quarterly	Safety Officer/ Laboratory Manager
		- Training workers on the correct transfer and handling of fuels and chemicals and the response to spills	- Number of staffs trained on spill management	- Quarterly	Safety Officer/ Laboratory Manager
Air pollution	Air pollution from aerosol generated activities , health care waste incineration and volatile chemicals	- Ensure proper handling of specimen and use standard laboratory practice to avoid/minimize release of aerosols and organic solvents to atmosphere (use of bio-safety cabinet) as recommended in WHO Biosafety Manual.	Percentage of trained laboratory staffs presence of regularly maintained BSC Presence of approved standards laboratory practices	Quarterly	-Laboratory Manager/ Supervisor Environmental Management Office Woreda FECC Office
		- Ensure adequate ventilation in laboratories and treatment areas	-Number of functional ventilation systems in place	Quarterly	Environmental Management Office Woreda FECC Office
		Use appropriate incinerator to treat health care wastes containing organic compounds	Observing the appropriateness of incinerator used and incineration practice	Quarterly	Woreda FECC Office
		Provide fume hood if necessarily for chemical processing	Presence of regularly maintained fume hood	Quarterly	Woreda FECC Office
Occupational health and Safety issues	Occupational health and safety risks on health care providers and supportive staff due to improper work procedures, healthcare	- - Adopting and implementing safety guideline or manuals from OSH guideline and WHO laboratory biosafety manual.	presence of approved guideline or manual and effectiveness evaluation records	Monthly	Woreda FECC Office & Health Office

Project Stage/ Components	Impacts	Mitigation Measures	Monitoring Indicator	Frequency of monitoring per site	Institution to Monitor
	waste management	Provide appropriate PPE for all staffs	-Number of workers properly utilizing PPE		
		Provide continuous training for all staffs on biosafety and biosecurity	number of trained staffs Presence of training Evaluation records	annually	Woreda Health Office
		- Organize and implement medical surveillance which includes medical service and immunization programs	presence of effective medical services and immunization programs	annually	Woreda Health Office Safety Officer/ Lab Manager
		- develop and implement safety standards.	Presence of approved safety standards	Annually	Safety Officer/ Lab Manager/ Woreda Health Office
		Implement engineering control systems like primary and secondary barriers	-Presence appropriate primary and secondary barriers. -Regular Maintenance records	Annually	Regional health bureau/ Woreda Health Office
Community Health and environmental risks	- Environmental pollution and community health risks due to improper waste disposal and specimen handling and transportation.	- Adhere to good microbiological techniques as recommended in WHO Biosafety Manual -	evaluation record as the laboratory practices adhered to WHO biosafety manual	Quarterly	Woreda FECC Office Woreda Health Office Safety Officer/ Lab Manager
		Develop and implement Risk management strategies for biological, physical, and chemical releases during laboratory operation that aligned with WBG EHS Guidelines for Community Health and Sa	Presence of risk management strategies	Annually	Regional health bureau/ regional environmental protection authority

Project Stage/ Components	Impacts	Mitigation Measures	Monitoring Indicator	Frequency of monitoring per site	Institution to Monitor
		Implement triple packaging systems for secure transportation of specimen Provide appropriate cars for sample transportation (see also annex 9)	Presence of appropriate triple packaging box Presence of car for sample transportation	Quarterly	Woreda FECC Office Woreda Health Office Safety Officer/ Lab Manager
		-Conduct civic health education to patients and the general public	- Number of awareness meetings Conducted	Quarterly	Woreda FECC Office Woreda Health Office Safety Officer/ Lab Manager
		Develop and implement chemical hygiene plan	Presence of appropriate chemical management plans	Quarterly	Woreda FECC Office Woreda Health Office Safety Officer/ Lab Manager
		Secure all waste throughout the waste management chain and provide adequate security to prevent scavenging	-Presence of designated and secured disposal sites and water quality compliance to national standard	Quarterly	Woreda FECC Office Woreda Health Office Safety Officer/ Lab Manager
	Risk due to poor laboratory practice	Minimize risk by meeting the requirements indicating in the bio-safety manual of WHO explained above.	Observation of laboratory practice against the WHO standard	Semi-annually	RHB
Potential risks associated with BSL 2	Potential risks associated with BSL 2	Implement the facility containment devices ,and administrative controls BSL-2 labs	the facility containment devices ,and administrative controls implemented	Annually	Safety Officer/ Lab Manager

Project Stage/ Components	Impacts	Mitigation Measures	Monitoring Indicator	Frequency of monitoring per site	Institution to Monitor
Laboratories operation	Laboratories operation can cause disease for staff and community	Good Microbiological Practices for the BSL 2 Laboratories	Good Microbiological practiced	Annually	Safety Officer/ Lab Manager
		Use Personal Protective Equipment during performing activities in BSL 2 Laboratories	Personal Protective Equipment during performing activities in used	Annually	Safety Officer/ Lab Manager
		Use laboratory Secondary Barriers for BSL2 laboratories	Secondary Barriers used	Annually	Safety Officer/ Lab Manager
Operation of laboratory	escaping of infectious agents from BSL-2 laboratories cause health problem	Provide training on handling infectious agents and waste handling, transportation, and storage	training on handling infectious agents and waste handling, transportation, and storage Provided	Annually	Safety Officer/ Lab Manager
		Maintain and calibrate all equipment periodically	Equipment periodically Maintained and calibrated	Annually	Safety Officer/ Lab Manager
		Provide vaccines or therapeutic measures for all risks	vaccines or therapeutic measures for all risks Provided	Annually	Safety Officer/ Lab Manager
		Sterilize all equipment by autoclave or chemical disinfection	Equipment sterilized	Quarterly	Safety Officer/ Lab Manager
		Establish biosecurity system place	biosecurity system placed	Once	Safety Officer/ Lab Manager
Emergency preparedness and response	Lack of emergency management can cause fire, devastation, injury and death	-Develop and implement emergency management plans.	Presence of emergency plan	Quarterly	Woreda FECC Office & Health Office
		-Regular drills exercise would constantly follow on various possible incidences. This will test the response of the involved stakeholders. Such drills will keep them alert and they will become more responsive to in the case of incidences.	Presence of training records or photographs on drill exercise	Quarterly	Woreda FECC Office & Health Office
		-Develop and implement chemical management plan.	Presence of approved plan	Annually	Woreda FECC Office & Health Office

Project Stage/ Components	Impacts	Mitigation Measures	Monitoring Indicator	Frequency of monitoring per site	Institution to Monitor
		-Develop and implement Medical insurance and compensation	Percentage of injured workers that received medical services and compensation	Annually	Public servants social security agency and regional health bureau
		-Develop evacuation procedures to handle emergency situations.	Presence of evacuation procedures	Quarterly	Woreda FECC Office & Health Office
		-Provide emergency materials like first aid kits, chemical and biological spill kits, emergency shower and eye wash, fire controlling systems,	Availability of appropriate emergency materials at facility levels	Quarterly	Woreda FECC Office & Health Office
		-Develop and implement emergency reporting systems	Presence of records	Quarterly	Woreda FECC Office & Health Office
		-Use signage to warn staff and/ or visitors that are not involved in laboratory work of dangerous places.	Presence of posted signage on appropriate places	Quarterly	Woreda FECC Office & Health Office
During Decommissioning					
Water	-Creation of stagnant water Pools conducive to mosquito breeding	Fill lower spots that may be created during dismantling and restoration of site	Check the creation of stagnant Extent water pools	Twice during dismantling and Restoration of sites	Woreda health office
Health and safety	Accidents during dismantling and restoration of site	Twice during dismantling and restoration of sites	No. of accidents in a month	Twice during restoration of sites	Woreda FECC Office & Health Office

Biannual review workshops will be conducted at Federal and regional levels with the objectives to:

- Assess project performance in complying with ESMF procedures, learn lessons, and improve future performance; and
- Assess the occurrence of, and potential for, cumulative impacts due to the proposed sub- projects and other development activities in the project area.

The participants of the ESMF review workshop are project implementing agencies whose subprojects have environmental and social concerns and are responsible for the ESMF implementation at all levels. Regional workshop will be organized by regional environment office. Biannual review workshop will be organized towards the end of the year. Besides, the World Bank, as necessary, will periodically conduct reviews of the implementation of the ESMF.

For the effective implementation of the ESMF a regular and period follow up is required. The objective of this is to:

- Alert project authorities by providing timely information about the success or otherwise of the
- Environmental management process outlined in this ESMF. This will ensure continuous improvement to ACRIFP environmental and social management process during the life cycle of the project.
- Make a final evaluation in order to determine whether the mitigation measures incorporated in the technical designs and the ESMP have been successfully implemented.

Table 8: Health Care Waste/ Laboratory Waste Management and Monitoring Plan

Mitigation measures	Responsible Authority for implementation	Responsible Authority for Monitoring	Recommended Frequency/times of Monitoring
Develop specifications and standards for waste management equipment and supplies	FMoH/ RHB/EPHI	Continuously during specifications and standards development	One Draft and final Standards and Specification for each laboratories
Develop facility based plans for regional labs.	FMoH/ RHB/EPHI	Continuously during development of plans	Draft and final Plans
Construct two chambers. Rotary kiln type/ similar incinerators for all Regional Labs	FMoH/ RHB/EPHI	During design and during construction	Approved designs and constructed incinerators

Purchase initial supplies for waste management for all regional labs	FMoH/ RHB/EPHI	Once on making Estimates and requisitions. -Once after purchase.	Purchase requisitions, delivery notes and receipts
Purchase Occupational Health and Safety /Personal Protective Equipment. (PPEs)	FMoH/ RHB/EPHI	• Once on making estimates and requisitions • Once after purchase	-Number of signs displayed in appropriate places -Laboratory safety Manual. - Number of workers provided with and using protective clothing and safety equipment.
Procure and install water storage tanks	FMoH/ RHB/EPHI	Once on making Estimates and requisitions. -Once after purchase -During construction	-Purchase requisitions, delivery notes and receipts Contract and Specifications
Develop and implement public (including indigenous people) social mobilization/ awareness	FMoH/ RHB/EPHI	Continuously during preparation of plans and during implementation	Number of people accepting and participating in the project
Ensure set-up of laboratory is conducive for easy and safe working	Laboratory Manager	Monthly	Number of accidents related to laboratory set- up
Availability of appropriate laboratory chemicals / materials to avoid or minimize waste	Laboratory Manager	Monthly	Number of items purchased according to recommended list
	FMoH/ RHB/EPHI	Quarterly	Number of items purchased according to recommended list
Minimize movement of people in the work area	Laboratory Manager	All the time	Number of times unauthorised persons found in laboratory
Use colour coded waste bins in appropriate positions	FMoH/ RHB/EPHI	Quarterly	Number of bins in recommended places
Segregation and storage of waste into marked bins	Laboratory Manager	Monthly	Number of waste streams used
Place disposable and re-usable materials separately	Laboratory Manager	Monthly	Number of cases of misplacement of re-usable
Disinfect re-usable materials such as slide holders, forceps etc.	Laboratory Manager	Monthly	Number of disinfections done per month
Follow steps and times for waste movement, storage and internal transportation	Laboratory Manager	Monthly	Frequency of waste Waste movement
Keep infectious (e.g. TB lab specimens and wastes) away from human contact	Laboratory Manager	Weekly	Number of reported infection cases Inspection report

Sterilize or disinfect waste before it leaves the laboratory	Laboratory Manager	Weekly	Disinfections statistics Inspection report
Discard contaminated materials and sputum containers in 5% phenol disinfectant or as recommended.	Laboratory Manager	Weekly	Number of disinfections done per day. Inspection report
Disinfect TB work surface areas with appropriate chemicals or methods.	Laboratory Manager	Daily	Number of disinfections done per day
Ensure internal safe movement of covered carts/bins for waste	Laboratory Manager	RPH Lab/RHB	Quarterly
Ensure availability of staff specifically designated for waste movement	Laboratory Supervisor	Laboratory Manager	Monthly
Ensure availability and use of appropriate tools, protective wear and safety equipment	Laboratory Manager	RPH Lab/ RHB	Quarterly
Tightly close and secure waste bins to avoid waste spills during transportation	Laboratory Supervisor	Laboratory Manager	Daily
Provide covered trucks for movement of waste to distant disposal site where necessary	RPH Lab/ RHB	FMoH/ EPHI	Every six months
Follow defined routes of waste (loaded carts) movement	Laboratory Supervisor	Laboratory Manager	Daily
Ensure availability of washing and disinfecting material for staff	Laboratory Supervisor	Laboratory Manager	Daily
Ensure availability and use of appropriate tools and PPE for personnel at disposal sites	Laboratory Manager	RPH Lab/ RHB	Quarterly
Ensure appropriate method of treatment is used for each type of waste	Laboratory manager	FMoH/RHB	Monthly
Cover disposal pits when half full to prevent access by people, animals and birds.	Laboratory Supervisor	Laboratory manager	As appropriate, just before pits are covered
	Laboratory manager	FMoH/RHB	Monthly
Line disposal pits and provide under drains to prevent water pollution from leachate	Local municipal Authority	FMoH/RHB	Monthly

Install incinerators with air pollution treatment facilities	RHB	FMoH	Monthly
All year round accessibility to disposal site.	Local municipal Authority / local Environmental protection offices	FMoH/FFECCA	Biannually
Location of disposal site to be: • Far from habited areas • On a leeward side • Far from reach of animals • Low water table sites	Local municipal Authority / local Environmental protection offices	FMoH/FFECCA	As necessary during disposal facility sighting
General Compliance			
Use of appropriate technology	FMoH/RHB	FFCCC	Quarterly
General health and safety of workers, employees and public	FMoH/RHB	FFCCC	Quarterly
Nuisance (air pollution, dust, smell and aesthetics	FMoH/RHB	FFCCC	Quarterly
Water pollution	FMoH/RHB/Zonal water, energy and irrigation Authority	Ministry responsible for Water Resources Ministry or department responsible for environment	Quarterly

6.3.1 Health Care Waste/ Laboratory Waste Management and Monitoring Plan

The table 8 above indicates mitigation measures of project impacts due to the health care waste, responsible institution for implementation of the measures, monitoring and frequency of monitoring is indicated.

6.4 Chance Finds and GRM Procedures

6.4.1 Procedure for the management of Chance Finds

It is anticipated that the construction and operational phase activities of the proposed BSL 2 Laboratories project may arise certain types of complaints by the neighborhood community in relation to construction activities (traffic & noise), waste management (both construction & operational waste), and other unpredicted sources of complaint. This section describes the procedures, roles and responsibilities for addressing such grievances and resolving disputes. Every aggrieved person shall be able to trigger this mechanism to quickly resolve their complaints.

The Contractors are responsible for familiarizing themselves with the following “Chance Finds Procedures”, in case culturally valuable materials are uncovered during excavation.

- Stop work immediately following the discovery of any materials with possible archaeological, historical, paleontological, or other cultural value and notify findings to project manager and relevant authorities;
- Protect artifacts’ as well as possible using plastic covers, and implement measures to stabilize the area;
- Prevent and penalize any unauthorized access to the artifact
- Restart construction works only upon the authorization of the relevant authorities;

Requirements for chance finds are also outlined in the Act. Article 41 which states that: “Any person who discovers any cultural heritage in the course of excavation connected with mining, explorations, building works, road construction or other similar activities would report to the Authority and protect and keep same intact until the Authority takes over to properly deal with them. The Authority would take all appropriate measures to examine and examine and register the cultural heritage. Where the Authority fails to take appropriate measures within 6 months, the person that discovered the cultural heritage will not have responsibility on the cultural heritage and can submit written application with a full description of the situation to the Regional Government official.

6.4.2 GRM Procedure

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

During the construction phase of the proposed BSL 2 laboratories project, the proponent (FMOH PHID I) and the contractor will jointly set up a project specific GRM with a team comprising of construction supervisor, and delegated officers from the PHID who will receive and log, and address any disputes, conflicts or concerns arising from stakeholders that may be aggrieved by the project. During the operation phase of the laboratories, the grievance process steps outlined below in figure will be used to manage all the grievances. This GRM will have accountability mechanism for handling issues, disputes, and complaints. It will be accessible so that individuals, workers, communities, and/or civil society organizations that are being aggrieved by any activities of the BSL 2 laboratories operation can use it.

Monitoring will be undertaken by FMOH (PHID directorate), Ministry of Environment, Forest and Climate Change (now Environment, Forest and Climate Change), Regional offices responsible for environment, regional health bureaus considered as "third party monitoring" with no regulatory mandate. Another government agency that may undertake "third party monitoring" is the Ministry of Labour and Social Affairs (MOLSA). This ministry has authority to inspect any facility for compliance with national requirements on safety in workplaces.

Monitoring will be done through site inspection, review of grievances logged by stakeholders and ad hoc discussions with potentially affected persons such as construction workers, residents near the hospitals, patients and healthcare staff.

Frequency: Monitoring will be undertaken monthly over the 3 years construction period.

Audits: 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 but not more than 36 months after completion of construction, according to EIA Regulations. Both construction and post-construction audits can be conducted internally by PHID/MOH or by a consultant hired by MOH.

Reporting: Monthly monitoring reports would be compiled by PHID/ FMOH's Project Coordination Team and shared with FMoH and EPHI or other interested stakeholders. The

FMOH will periodically submit the audit report to the Environment, Forest and Climate Change Commission as per the guidance of the EIA Regulations, 299/2002.

Grievance Mechanism

This section describes the procedures, roles and responsibilities for addressing grievances and resolving disputes. Any project affected person can trigger this mechanism to quickly resolve complaints.

The objectives of the grievance process are to:

- Ensure that appropriate and mutually acceptable corrective actions are identified and implemented to address complaints;
- Verify that complaints are meet according to the corrective actions proposed in the ESMF;
- Avoid the need to resort to judicial proceedings.

The grievance mechanism at all the project sites will be fed from three main sources:

- Community residents, patients or health workers;
- Supervising engineer or contractor.
- Monitoring team who will forward issues/concerns identified during supervision.

Steps of the grievance process are described below. A flow chart outlining the main actions and decision points is shown in figure 3 below.

Step 1: Receipt of complaint

A verbal or in written complaint from any party or individual will be received by the construction supervisor and complaint will be recorded and kept on site. The log will indicate grievances, date lodged, and action taken to address complaint, reasons that the grievance was not acted on or information provided to the person or entity that lodged complaint and date the grievance was closed. The Grievances would also be lodged at any time directly to the office of project supervisor.

The process for lodging a complaint is outlined in the diagram below:

- Project supervisor receives complaint(s) and records it in log sheet;

- Project supervisor review the recorded complaint;
- Complainant signs on the log sheet to confirm grievance was accurately recorded.

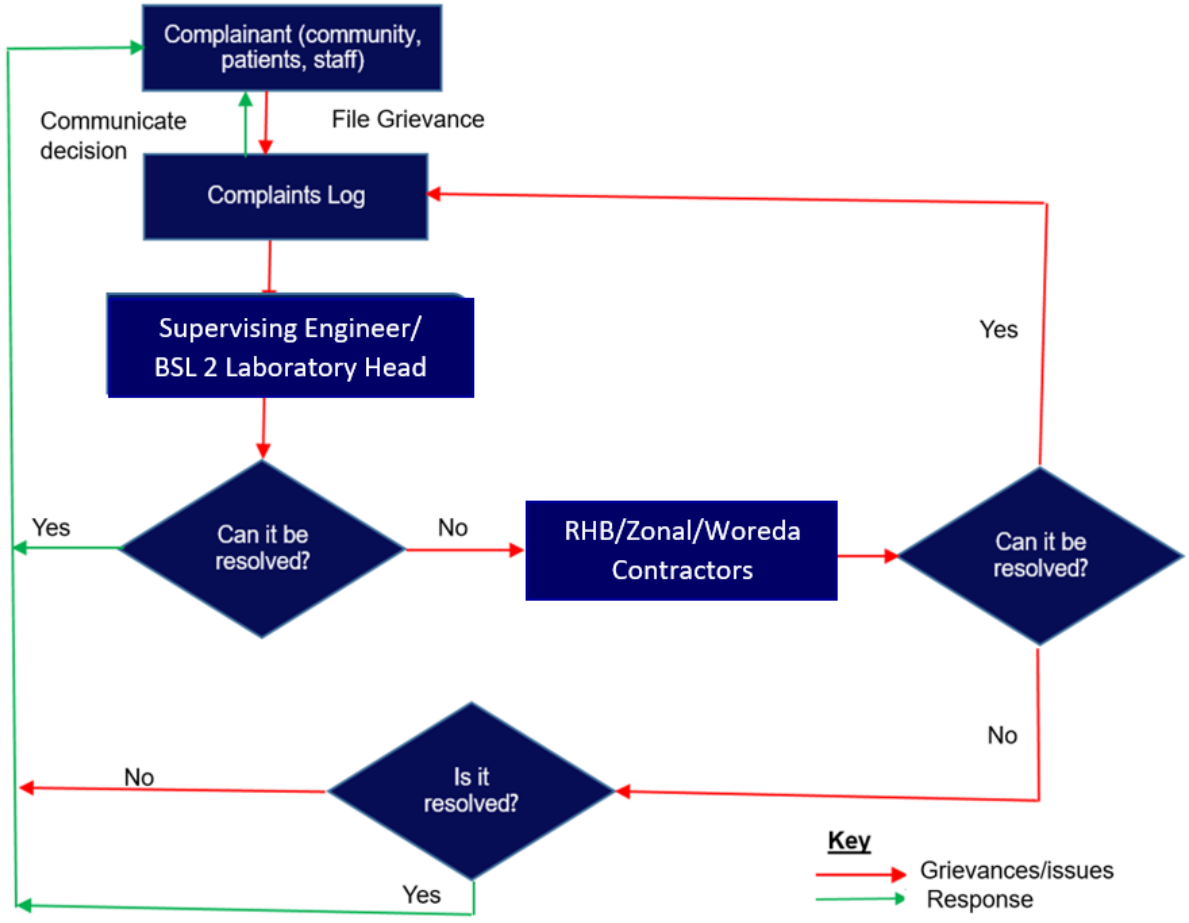

Figure 3: Grievance management mechanism

Step 2: Determination of corrective action

A grievance can be solved at this stage. The project supervisor or BSL 2 laboratory (operational phase) heads will determine corrective action in consultation with the person who lodged the grievance. Remedial action(s) and timeframe within which decision has to be made has to be and the party responsible for implementing them must be recorded in the complaint log. Grievances will be resolved and status reported back to the person or entity that lodged the complaint within a week. If more time is required this will be communicated clearly and in advance to the affected entity or individual. For cases that are not resolved within the time stipulated, detailed investigations will need to be undertaken and results would be within one month from lodging a grievance. The grievance beyond the capacity of the project supervisors

or BSL 2 laboratory (operational phase) heads are communicated to a higher level as indicated on the diagram of grievance management mechanism indicated above.

Step 3: Meeting with the complainant

The proposed corrective action and the timeframe in which it is to be implemented would be discussed to proceed with the corrective action will be sought.

Step 4: Implementation of corrective action

Agreed corrective action will be undertaken by the project or its contractor within the agreed timeframe. The date the corrective action has been taken will be recorded in the log against the complainant's grievance.

Step 5: Verification of corrective action

To verify satisfaction, the affected entity/ person will be asked to apply to a higher level if not satisfied with the corrective action.

Step 6: Action by MOH/PHID and project contractors

If the Project supervisor cannot solve the grievance, he will refer it to MOH/PHID through the Supervising Engineer. It is believed all possible grievances can be solved at this level.

6.5 Capacity Building and Technical Assistance

6.5.1 Institutional Capacity Assessment

The implementation of Regional laboratories (sub projects) is expected to fulfil the safeguard policies requirements stipulated in the ESMF prepared for the Africa CDC Regional Investment Financing Program. However, the regions have no enough capacity to supervise and implement the implementation of these policies. The staff assigned to implement the sub-projects at the federal and regional levels would therefore receive training on social and environmental issues related to this project in order to properly implement the safeguard policies and also carry out proper monitoring. There is also the need to provide specific training on environmental management and impact assessment to the experts from Ministry of Health, the Ethiopian Public Health Institute and the Regional Health Bureaus in the topics in environmental screening supervision and implementation of the ESMF. Similar training would also be given to experts at the regions to oversee proper implementation of the mitigation measures to minimize project impacts.

6.5.2 Training and Awareness Raising

Creating awareness among the contractors and regional supervisors and the Regional Health bureaus on the impacts and action that would be taken to minimize impacts of the project is very crucial. To this effect there is a need to develop a training plan to build the capacity who in one way or another will participate in the execution and supervision of the proposed project. Depending on the capacity building needs identified during the Performance Reviews or M&E, refresher courses will also need to be given in the course of sub-project implementation.

Areas identified for training include:

- Training on the role of supervisors and implementers during the screening, planning, reviewing, implementation and monitoring process of the sub- Projects;
- Training on environment related national policies, laws, regulations policies that would be respected during the implementation of sub-projects;
- Training on the World Bank environmental and social safeguards policies that will be triggered by Africa CDC Regional Investment Financing Program.
- Training on environmental and social assessment, ESIA approval processes, reporting and monitoring; and preparation of environmental management plan see table 9;

6.5.3 Technical Assistances

For effective implementation of the ESMF, technical assistance is also required at region to build the capacity and discharge their responsibilities as per the requirements set out in this ESMF. To this effect general technical assistance will be given to experts at the federal and regional levels. This assistance includes training on monitoring of the effective implementation of the mitigation measures set out in the ESMP and in monitoring and supervision of the ESMF implementation to carry out on a bi-annual basis.

The budget on specific and general technical assistance will be part of the subprojects budget and will not be included in budget earmarked to implement ESMF. The ACRIFP is planned to be implemented in 3 years. Budget required for capacity building and for conducting training and awareness workshops to implement the ESMF during the 3 years project life is indicated in the table below:

Table 9: Estimated budget for the implementation of the ESMF

No	List of activities	Estimated Budget in US$			Total
		1st year	2nd year	3rd year	
1	Awareness raising and project launching workshop				
1.1	Federal level	10,000			
1.2	Regional level	80,000			
Sub-total		90,000			90,000
2	Training of Trainers (ToT) on ESMF implementation				
2.1	Regional level	80,000			
2.2	At the level of project site	20,000			
Sub-total		100,000			100,000
3	Training on social and environmental screening and approval of subprojects				
3.1	Federal	20,000			
3.3	Regional	40,000			
	Sub-total	**60,000**			**60,000**
3	Annual review Workshops, supervision and monitoring				
3.1	Regional level	5,000	5,000	5,000	
	Sub-total	5,000	5,000	5,000	15,000
	Total	**255,000**	**5,000**	**5,000**	**265,000**

The overall budget estimate for capacity building and conducting workshops for the implementation of ESMF as indicated in the above table is 265,000 US$.

7 Protocol for Conducting Environmental and Social Audits under Africa CDC Program for BSL2 labs to be financed by the Program in Ethiopia

7.1 Environmental auditing and Scope of audits for World Bank projects

An environmental audit is a methodical examination of environmental information about an organization, a facility, or a site, to verify whether, or to what extent, they conform to specified audit criteria. The criteria may be based on local, national or international environmental standards, national laws and regulations, permits and concessions, internal management system specifications, corporate standards, or guidelines of organizations such as the World Bank. The reasons for undertaking an audit and the aims to be achieved will determine the audit criteria.

A prerequisite to successful implementation of any aspect or type of environmental audit is the commitment of management to maintain or move toward sound environmental practices. This shows itself through the operations of the company, facility or site, management attitudes to environmental matters, and the level of commitment shown by staff. As a systematic process of obtaining and evaluating information about the environmental aspects of an operation, an organization or a site, the environmental audit will generally require enough and appropriate information about the operation, organization or site; adequate resources available to support the audit process; adequate cooperation from the company or other entity that is being audited (auditee); and an audit protocol (e.g. a checklist or questionnaire).

An environmental audit is undertaken by auditors and is based on objectives defined by the client, who might also be the auditee. The audit criteria would be agreed upon between the auditors and the client and communicated to the auditee along with the aims and scope of the audit. The auditors would be objective and independent of the site or activity being audited, although they may sometimes be part of the same company. Information gathered during the audit would always be treated as confidential. It is presumed that the auditors will follow systematic procedures (e.g., by using an audit protocol), so that a similar audit performed by different auditors would yield consistent results. Different types of audits will use different methodologies and different ways to obtain and evaluate information about the subject matter of the audit. Based on the audit criteria, auditors collect information and documents evidence to determine whether audit criteria have been met. These findings are the basis of the report to the

client. An audit takes place during a short period of time and with limited resources. It is thus important to assess the reliability of audit conclusions and keep the inherent uncertainties in mind when using the audit results. The compliance audit is the type of audit that most directly assesses compliance against criteria derived from laws and regulations, applicable standards, permits and concessions, or guidelines from organizations such as the World Bank.

For Bank projects, a set of national or international standards and regulations may be used as audit criteria. The scope, objectives and criteria must be defined on a case-by-case basis, but the investigations would normally encompass an evaluation of all environmental, and health and safety, concerns in terms of past and current impacts and compliance with relevant standards. To fulfil the planning aspect, the audit would include tests and measurements as well as sampling and laboratory testing. Also, corrective actions emerging from the audit investigations would normally be described in detail rather than having company management decide how non-conformities are to be corrected.

An environmental mitigation plan or an environmental management plan would therefore usually form an important part of the audit report. Here, measures necessary for bringing the project up to an acceptable environmental standard, and their costs, would be discussed and prioritized. Further, measures needed to provide assurance that environmental issues will be controlled in an acceptable manner in the future would be addressed. Such aspects can include monitoring programs, environmental reporting requirements, training of personnel, or organizational aspects like the appointment of an environmental officer or the implementation of a formalized environmental management system. To get a comprehensive view of the environmental situation at and around a site, and to help in setting mitigation priorities, auditors would consult with national and local regulatory authorities and, as appropriate, with local community representatives as part of the auditing process. Consultation with community representatives is particularly important when the Bank or auditors suspect that an operation represents a serious local health or safety hazard. The Bank expects findings to this effect to be reported to authorities and disclosed to the public. For Bank projects, the environmental audit report would normally include prioritized recommendations for mitigation and other actions, and their cost. The report would be an unbiased and objective evaluation, and neither the client nor the auditee would be allowed to change the main conclusions of the audit team.

7.2 The Environmental Audit Protocol

This environmental audit protocol is a tool which will assist the Ethiopian Ministry of Health and Ethiopian Public Health Institute while conducting environmental audits in BSL 2 labs which will be financed by Africa CDC Program. It includes a checklist containing detailed questions and procedures to be followed while conducting the ES audit. The protocol will serve as a management tool for Ethiopian Ministry of Health and Ethiopian Public Health Institute for measuring and improving environmental performance by correcting deficiencies uncovered by the audit. This audit protocol will be used as a planning tool to assist the auditor in understanding the requirements for conducting a comprehensive audit. This protocol would not be used as a substitute for the applicable regulations. This audit protocol is a vehicle for obtaining information covering all relevant aspects of the specified audit. It provides a valuable framework within which to work, but it would not restrict the auditor from identifying and assessing aspects not covered in the protocol. Audit protocols or audit questionnaires provide the basis and structuring for the audits.

7.3 Checklists for the audit protocol and methodology for auditing

While conducting the environmental and social audit, the methodology to be followed include among others interviews with selected laboratory workers, reviewing relevant documents and the laboratory results, site inspection in the BSL 2 laboratories, examination of storage areas, and discussions with the appropriate regulatory authorities responsible for monitoring medical and hazardous wastes. Local authorities and community representatives are also a good source of information. The lead auditor will communicate with the auditee to arrange all practical arrangements, including date and time for the visit, travel and lodging arrangements, contact person of the auditee, the agenda for the site visit, and any special rules to be obeyed, like safety precautions, or whether photographing is allowed. The auditor would normally receive background information from the client or auditee to become acquainted with processes, facilities, past environmental problems and other information deemed relevant for proper preparation of the audit team. These issues are sometimes discussed a few weeks before the actual site visit in an initial meeting between the auditee and the auditor.

The audit team would meet at the end of each day to discuss findings and preliminary conclusions and to plan the strategy for the next day. The activities at site conclude with a

closing meeting attended by the same people as the opening meeting. The meeting would be brief and would present the results of the audit as they will appear in the audit report. Findings would always be substantiated by concrete evidence. If all non-conformities to the audit criteria are well documented and discussed prior to the closing meeting there will be little need for lengthy discussion of the conclusions. The auditor would stick to the conclusions of the team unless something is misunderstood. Observations not supported by evidence may be presented as opportunities for improvement. If suggestions for improvements or remedial action are included in the TOR these may also be outlined in the closing meeting (see annex 7). The lead auditor will notify management as to when a draft audit report will be submitted. In the post-audit stage, the audit report is completed based on the conclusions of the closing meeting. A draft report is usually submitted to the auditee and the client for comments. The audit report will state the audit objectives, scope and criteria, identify persons involved from both the auditor's and the auditee's side, the methodologies and procedures applied, and the main findings and conclusions of the audit, with a list of bodies consulted during the audit process.

Observations which cannot be supported by evidence or which appear to be one-off cases would be investigated to determine if they are symptomatic of actual performance. Observations supported by evidence of practices that fail to meet the audit criteria are termed "non-conformities" and form the basis of the conclusions of the audit report. Non-verifiable observations or minor issues are often called "findings "and, if presented in the audit report, they would clearly be presented as such. Checklist will be used as a guiding tool to collect relevant data during environmental auditing. The checklist delineates what would be evaluated during an audit. The TOR and the checklist are annexed (Annex 7 & 8)

8 Disclosure Policies and Procedures

This ESMF will be disclosed by the client and the external website of World Bank on 20 June 20, 2019. The final (cleared) ESMF will be disclosed on 20 June at the Government's website to make it accessible to any person interested to refer this document. The Ministry of Health will also distribute this document to relevant government institutions. Besides, for purpose of discloser key findings of the draft ESMF and the mitigation strategies for the findings were presented to local community and stakeholders at Tigray (on April 19, 2019), Oromia (on April 22, 2019), SPNNRS (on April 19, 2019), Somali (April 26, 2019), Gambela (April 25, 2019), and Benishangule-Gumuz (April 25, 2019) regional states at the respective regions (proposed construction sites).

The objective of the public consultation was to solicit the views and opinions of the participants towards the construction of the BSL 2 laboratories and the draft ESMF for construction of the BSL 2 laboratories. The participants were from regional health bureaus, zonal environmental and climate change office, zonal/local government administration, tourism and culture office, zonal water and energy office, and community elders. After presentation, participants were invited to raise their concern if any. The concerns of the participants among other include about effect of solid and liquid waste handling and disposal, impact of the construction activities on community, and the implementation of proposed mitigation for the impacts identified and monitoring system. The approach (methods) for addressing the concerns of the community was clearly presented (See Annex 10 for consultation minutes).

To address their concerns, they informed that the health facilities/the BSL2 labs will:

- Develop and implement appropriate plans and strategies for waste minimization and segregation
- have standard operation and decontamination procedures and manuals
- properly select disposal sites
- will adhere to recommended and international best practices on waste disposal practices
- use appropriate efficient incinerator to treat health care wastes containing organic compounds

Annexes

A. Annex 1: Environmental and Social Screening Form

The Environmental and Social Screening Form (ESSF) has been designed to assists in the evaluation of sub projects for the East Africa Public Health Laboratory Networking Project.

The form is designed for assessment of environmental and social impacts and their mitigation measures, if any, so that requirements for further environmental analysis can be determined.
This form must be completed by the District Environmental Management Officer or district staff appropriately trained to do so and in consultation with the key stakeholders of the subproject.
The form will form part of the approval requirements for implementation of the subproject activities.
PART A: GENERAL INFORMATION

1. Name of project site: ……..
2. Name of the project location: ……..
3. Name of Wareda ……..
4. Name of District ……..
5. Name of Executing Agent ……...
6. Name of the Approving Authority ……..

Details of the Person Responsible for Completing this ESSF:

1. Name: ……..
2. Job title: ……...
3. Telephone Number: ……...
4. E-mail Address: ……
5. Date: ……..
6. Signature: ……..

PART B: Brief Description of the Project
Please provide information on the type and scale of the sub-project (area, required land and approximate size of total building floor area).
Provide information about the nature of activities during the construction of the facilities including support/ancillary structures and activities required to build it, e.g. need to quarry or excavate borrow materials, laying pipes/lines to connect to energy or water source, access road etc.

PART B: BRIEF SESCRIPTION OF THE ENVIRONMEENTAL SITUATION AND IDENTIFICTION OF ENVIRONMENTAL AND SOCIAL IMPACTS
Describe the sub-project location, sitting, surroundings (include a map or even a sketch map)
escribe the land formation, topography, vegetation in and adjacent to the project area.
Estimate and indicate where vegetation may have to be cleared.

No	Description	Yes	No	Not known
PART C. ENVIRONMENTALLY SENSITIVE AREAS OR THREATENED SPECIES THAT COULD BE ADVERSELY AFFECTED BY THE PROJECT				
1	Intact natural forests			
2	Riverine forest and river banks			
3	Surface water courses, natural springs			
4	Wetlands (lakes, rivers, swamp, seasonally inundated areas)			
5	Distance to the nearest wetland (lakes, river, seasonally inundated areas) less than 30 km:			

6	Area is of high biodiversity			
7	Habitats of endangered/threatened species for which protection is required under Ethiopian's' Laws.			
PART D. GEOLOGY, TOPOGRAPHY AND SOIL				
1	Direct cause or worsening of soil loss or erosion by the project			
2	Project will lead directly or indirectly to practices that could cause soil loss or erosion (e.g. soil erosion and pit formation from sand mining and brick moulding)			
3	Need to consult a soil scientist on the project			
4	Modification of slopes is required by the project			
5	Project will affect stability of slopes directly or indirectly			
6	Project is located where existing unstable slopes could be a azard			
7	Soil instability in the project area black cotton soil, earthquake,			
	landslide, subsidence			
8	Project will cause substantial increase in soil salinity			
9	Increase in chances of floods, poorly drained, low-lying,			
	depression or block run-off – water			
10	Soil contamination and pollution hazards will result from the			
	Project			
11	Risks of contamination and pollution from latrines, dump sites,			
	industrial discharge etc.			
12	Need to consult a geo-technical engineer			
PART E. LAND, TREES, VEGETATION AND PROPERTY (IN CASE OF AUXILIARY e.g. QUARRIES)				
1	There are farm lands in the project area			
2	Project will reduce or damage farm land			
3	Project will cause loss of vegetation, crops and fruit trees animals			
	and livestock			
4	Loss of trees for fire wood for brick curing, adding to			
	Deforestation			
5	Use of construction timber for supports, door/widows and			
	furniture contributing to deforestation.			
6	Project will cause loss of houses, infrastructures (shed, toilets,			
	granaries)			
7	Project will cause loss or interference with access, routes for			
	people, livestock etc			
8	Land in the project area is intensively developed			
9	The project will increase pressure on land resources			
10	The project will result in decreased holdings by small land owners			
11	A land use planner would be consulted			
PART F. SURFACE WATER QUANTITY AND QUALITY				
1	Project will increase demand or cause loss of available surface			
	Water			
2	Project will lead to additional discharges into surface water			
3	Project could cause deterioration of surface water quality			

4	Need to consult a hydrologist and/or water quality expert			
PART G.	GROUNDWATER QUALITY AND QUANTITY			
1	Project will increase demand or cause loss of available ground			
	water resources			
2	Project will cause natural or man-made discharge into ground			
	Aquifer			
3	Project could cause deterioration of ground water quality (e.g.			
	from human waste from toilets)			
4	Need to consult a hydrologist and/or water quality expert			
PART G.	GROUNDWATER QUALITY AND QUANTITY			
1.	Project will increase demand or cause loss of available ground water resources			
2.	Project will cause natural or man-made discharge into ground aquifer			
3.	Project could cause deterioration of ground water quality (e.g. from human waste from toilets)			
4.	Need to consult a hydrologist and/or water quality expert			
PART H.	AIR QUALITY			
1.	Project will pollute air directly (construction cement /dust)			
2.	Project will lead to practices that worsen air quality			
3.	Project will lead to a change in engine or fuel use that could cause serous air problems			
4.	Project will result in polluted and hazardous working environments for staff			
PART I.	NOISE			
1.	Noise is a problem in the project area The project will generate noise from construction activities			
2.	Project operation will result in increase in noise generation			
3.	Project could make people to move to high noise level area			
4.	Project could result in noisy working environments for staff			
PART J.	AQUATIC ECOSYSTEMS			
1.	Significant aquatic ecosystems (wetlands, rivers, streams, lakes or ponds) are in the project area			
2.	Project will affect the condition and use of ecosystems for human consumptions			
3.	Significant wetland ecosystems (marsh, swamp, flood plains, or estuary) are in the project area			
4.	Project will affect the use or condition of such wetlands			
PART K.	TERRESTRIAL ECOSYSTEMS			
1.	There are significant terrestrial ecosystem (forest, savannah, grassland or desert) in the project area			
2.	Project will affect the use or condition of such ecosystems			
PART L.	ENDANGERED/ THREATENED/RARE/ENDEMIC/SPECIES			
1.	Endangered species exist in the project area			
2.	Project will affect the habitant and number of such species			

PART M. MIGRATORY SPICES				
1.	Migratory fish, birds, or manuals use the project area			
2.	Project will affect the habitat and numbers of such species			
PART N. BENEFICIAL PLANTS, ANIMALS, INSECTS, PESTS AND VECTORS				
1.	There are non-domesticated plants and/or animals, used or sold by local people in the project area			
2.	Project will affect these species by reducing their numbers or habitant			
3.	There are currently problems with pest (plants or animals) in the project area			
4.				
5.	Plants or animals might become pests due to ecological changes brought by the project in the area			
6.	There are known disease problems in the project area transmitted through vectors			
7.	Project will increase vector habitat or population			
PART O. ENERGY SOURCE				
1.	The project will increase demand for conventional energy sources			
2.	The project will create demand for demand for other energy sources (wood and charcoal)			
3.	The project will promote supply of conventional energy sources			
PART P. RESOURCE DISTRIBUTION AND DEGRADATION				
1.	The project will increase demand for certain commodities within or outside the project area			
2.	The project will result in decrease of production for certain vital commodities			
3.	Project will use large amounts of natural resources (construction materials, water, land and energy			
4.	Adverse impacts of the project will be unequally distributed in the target population			
PART Q. EMPLOYMENT AND INCOME				
1.	The project will remove job opportunities from the area			
2.	The project will decrease income sources or means of livelihood			
PART R. LIVELIHOODS				
1.	People's assets or livelihoods will be affected			
2.	People will lose access to natural resources			
PART S. EXISTING AND MIGRANT POPULATION (IN CASE OF AUXILIARY WORKS)				
1.	There are people currently living in or near the project area			
2.	The project will affect people in or near the project area			
3.	There are currently mobile groups in the target population			
4.	The project will result in the movement of people in or out of the area			
5.	It is necessary to consult a sociologist			
1.	Cultural characteristics unique to the project area are understood			
2.	The project will adversely affect religious and/or cultural attitudes of area resident			
3.	The project will affect religious and or cultural sites or monuments			

4.	There special superstitions or taboos that will affect acceptance of the project			
5.	There are graveyards in the project area			
6.	There are historical buildings in the area			
PART U	TOURISM AND RECREATION			
1.	There is a significant degree of tourism in the area			
2.	There is unexploited tourism or recreation potential in the area			
3.	The project will adversely affect existing or potential tourist or recreation attractions			
PART V	GENERAL AND HAZARDOUS WASTES			
1.	The project will generate significant amounts of waste (rubble: concrete, bricks, blocks etc) during construction			
2.	The project will generate significant amounts of waste (e.g. plastics and packaging material) during operation			
3.	The project will produce hazardous wastes requiring special handling, storage, treatment and disposal methods			
4.	The project will cause spread of infection within and outside the facility requiring adherence to standards and precautions			
5.	Is there existing or planned hazardous solid wastes disposal facilities that could serve during the operation of the proposed BSL 2 laboratory			
6.	Is there existing or planned hazardous liquid wastes disposal facilities that could serve during the operation of the proposed BSL 2 laboratory			

For sub-projects that need special attention

Feature of Concern: Subproject or business plan	yes	No
likely to use pesticides or other agro-chemicals		
involves land acquisition, or loss of assets, or access to assets on the land		

Recommendations
Sub-project needs special attention: _____
Sub-project does not need special attention: _____

For subprojects of environmental and social concern

Will the Sub-project or business plan:	Yes	No
located within National Park or other designated wildlife area or buffer zone		
located in a Priority Forest Area		
involve draining of or disturbance to a wetland		
located within a recognized Cultural Heritage site or World Heritage site		
incorporates a dam		
involve use of hazardous laboratory chemicals		
involve pollution of or abstraction of significant volume of water from international waterways		

B. Annex 2: Environmental and Social Guidelines for Contractors

General

In addition to these general conditions, the Contractor would comply with any specific ESMP for the works he is responsible for. The Contractor would inform himself about such an ESMP, and prepare his work strategy and plan to fully take into account relevant provisions of that ESMP. If the Contractor fails to implement the approved ESMP after written instruction by the Supervising expert to fulfill his obligation within the requested time, the Owner reserves the Right to arrange through the Supervising expert for execution of the missing action by a third party on account of the Contractor. Notwithstanding the Contractor's obligation under the above clause, the Contractor would 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. In general, these measures would include but not be limited to:

- Minimize the effect of dust on the surrounding environment resulting from earth mixing sites, vibrating equipment, temporary access roads, etc., to ensure safety, health and the protection of workers and communities living in the vicinity dust producing activities.
- Ensure that 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.
- Ensure that existing water flow regimes in rivers, streams and other natural or irrigation channels is maintained and/or re-established where they are disrupted due to works being carried out.
- Prevent bitumen, oils, lubricants and waste water used or produced during the execution of works from entering rivers, streams, irrigation channels and other natural water bodies/reservoirs, and also ensure that stagnant water in uncovered borrow pits is treated in the best way to avoid creating possible breeding grounds for mosquitoes.
- Prevent and minimize the impacts of quarrying, earth borrowing, piling and building of temporary construction camps and access roads on the biophysical environment including protected areas and arable lands; local communities and their settlements. In as much as possible restore/rehabilitate all sites to acceptable standards.
- Discourage construction workers from engaging in the exploitation of natural resources such as hunting, fishing, and collection of forest products or any other activity that might have a negative impact on the social and economic welfare of the local communities.
- Implement soil erosion control measures in order to avoid surface run off and prevents siltation, etc.
- Ensure that garbage, sanitation and drinking water facilities are provided in construction workers camps.
- Ensure that, in as much as possible, local materials are used to avoid importation of foreign material and long distance transportation.
- Ensure public safety, and meet traffic safety requirements for the operation of work to avoid accidents.
- The Contractor would indicate the period within which he/she would maintain status on site after completions of civil works to ensure that significant adverse impacts arising from such works have been appropriately addressed.

The Contractor would 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.

Besides the regular inspection of the sites by the Supervising expert for adherence to the Contract conditions and specifications, the owner may appoint an Inspector to oversee the compliance with these environmental conditions and any proposed mitigation measures. State environmental authorities may carry out similar inspection duties. In all cases, as directed by the Supervising expert, the Contractor would comply with directives from such inspectors to implement measures required to ensure the adequacy rehabilitation measures carried out on the bio-physical environment and compensation for socio-economic disruption resulting from implementation of any works.

Work site/Campsite Waste Management

All vessels (drums, containers, bags, etc.) containing oil/fuel/surfacing materials and other hazardous Chemicals would be bonded in order to contain spillage. All waste containers, litter and any other waste Generated during the construction would be collected and disposed of at designated disposal sites in line with applicable government waste management regulations. All drainage and effluent from storage areas, workshops and camp sites would be captured and treated before being discharged into the drainage system in line with applicable government water pollution control regulations.

- Used oil from maintenance would be collected and disposed of appropriately at designated sites or be re-used or sold for re-use locally.
- Entry of runoff to the site would 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.
- Construction waste would not be left in stockpiles along the road, but removed and reused or disposed of on a daily basis.

If disposal sites for clean spoil are necessary, they would be located in areas, approved by the Supervising Expert, of low land use value and where they will not result in material being easily washed into drainage channels. Whenever possible, spoil materials would be placed in low-lying areas and would be compacted and planted with species indigenous to the locality.

Material Excavation and Deposit

The Contractor would obtain appropriate licenses/permits from relevant authorities to operate quarries or borrow areas.

The location of quarries and borrow areas would be subject to approval by relevant local and national authorities, including traditional authorities if the land on which the quarry or borrow areas fall in traditional land.

New extraction sites:

- Would not be located in the vicinity of settlement areas, cultural sites, wetlands or any other valued ecosystem component, or on high or steep ground or in areas of high scenic value, and would not be located less than 1km from such areas.
- Would not be located adjacent to stream channels wherever possible to avoid siltation of river channels. Where they are located near water sources, borrow pits and perimeter drains would surround quarry sites
- Would not be located in archaeological areas. Excavations in the vicinity of such areas would proceed with great care and would be done in the presence of government authorities having a mandate for their protection.
- Would not be located in forest reserves. However, where there are no other alternatives, permission would be obtained from the appropriate authorities and an environmental impact study would be conducted.

- Would be easily rehabilitated. Areas with minimal vegetation cover such as flat and bare ground, or areas covered with grass only or covered with shrubs less than 1.5 m in height, are preferred.
- Would have clearly demarcated and marked boundaries to minimize vegetation clearing.
- Vegetation clearing would be restricted to the area required for safe operation of construction work. Vegetation clearing would not be done more than two months in advance of operations.
- Stockpile areas would be located in areas where trees can act as buffers to prevent dust pollution.
- Perimeter drains would be built around stockpile areas. Sediment and other pollutant traps would be located at drainage exits from workings.
- The Contractor would deposit any excess material in accordance with the principles of these general conditions, and any applicable EMP, in areas approved by local authorities and/or the Supervising expert.
- Areas for depositing hazardous materials such as contaminated liquid and solid materials would be approved by the Supervising expert and appropriate local and/or national authorities before the commencement of work. Use of existing, approved sites would be preferred over the establishment of new sites.

Rehabilitation and Soil Erosion Prevention

- To the extent practicable, the Contractor would rehabilitate the site progressively so that the rate of rehabilitation is similar to the rate of construction.
- Always remove and retain topsoil for subsequent rehabilitation. Soils would not be stripped when they are wet as this can lead to soil compaction and loss of structure.
- Topsoil would not be stored in large heaps. Low mounds of no more than 1 to 2m high are recommended.
- Re-vegetate stockpiles to protect the soil from erosion, discourage weeds and maintain an active population of beneficial soil microbes.
- Locate stockpiles where they will not be disturbed by future construction activities.
- To the extent practicable, reinstate natural drainage patterns where they have been altered or impaired.
- Remove toxic materials and dispose of them in designated sites. Backfill excavated areas with soils or overburden that is free of foreign material that could pollute groundwater and soil.
- Identify potentially toxic overburden and screen with suitable material to prevent mobilization of toxins.
- 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.
- Minimize the long-term visual impact by creating landforms that are compatible with the adjacent landscape.

Minimize erosion by wind and water both during and after the process of reinstatement.

Compacted surfaces would be deep ripped to relieve compaction unless subsurface conditions dictate otherwise. Re-vegetate with plant species that will control erosion, provide vegetative diversity and, through succession, contributes to a resilient ecosystem. The choice of plant species for rehabilitation would be done in consultation with local research institutions, forest department and the local people.

Water Resources Management

- The Contractor would at all costs avoid conflicting with wa**ter demands of local commun**ities.

- Abstraction of both surface and underground water would only be done with the consultation of the local community and after obtaining a permit from the relevant Water Authority.
- Abstraction of water from wetlands would be avoided. Where necessary, authority has to be obtained from relevant authorities.
- Temporary damming of streams and rivers would be done in such a way avoids disrupting water supplies to communities downstream, and maintains the ecological balance of the river system.
- No construction water containing spoils or site effluent, especially cement and oil, would be allowed to flow into natural water drainage courses.
- Wash water from washing out of equipment would not be discharged into watercourses or roads drain.
- Site spoils and temporary stockpiles would be located away from the drainage system and surface runoff would be directed away from stockpiles to prevent erosion.

Chance finds procedure for culturally significant artifacts'

The Contractor is responsible for familiarizing themselves with the following "Chance Finds Procedures", in case culturally valuable materials are uncovered during excavation, including:

- Stop work immediately following the discovery of any materials with possible archaeological, historical, paleontological, or other cultural value, announce findings to project manager and notify relevant authorities;
- Protect artifacts' as well as possible using plastic covers, and implement measures to stabilize the area, if necessary, to properly protect artifacts'
- Prevent and penalize any unauthorized access to the artifact
- Restart construction works only upon the authorization of the relevant authorities.

Requirements for chance finds are also outlined in the Act. Article 41 which states that: "Any person who discovers any cultural heritage in the course of excavation connected with mining, explorations, building works, road construction or other similar activities would report to the Authority and protect and keep same intact until the Authority takes delivery thereof". The Authority would take all appropriate measures to examine, take delivery and register the Cultural heritage so discovered. Where the Authority fails to take appropriate measures within 6 months, the person that discovered the cultural heritage may be released from the responsibility by submitting a written notification with a full description of the situation to the Regional Government official.

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 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 Environmental and social impact. **Water Resources Management**

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For sub-projects that need special attention

Feature of Concern: Subproject or business plan	yes	No
likely to use pesticides or other agro-chemicals		
involves land acquisition, or loss of assets, or access to assets on the land		

Recommendations

Sub-project needs special attention: _____

Sub-project does not need special attention: _____

For subprojects of environmental and social concern

Will the Sub-project or business plan:	Yes	No
located within National Park or other designated wildlife area or buffer zone		
located in a Priority Forest Area		
involve draining of or disturbance to a wetland		
located within a recognized Cultural Heritage site or World Heritage site		
incorporates a dam		
involve use of hazardous laboratory chemicals		
involve pollution of or abstraction of significant volume of water from international waterways		

C. Annex 3: Subproject Eligibility Screening Checklist

Subproject Name: _____
Region: _____; Zone: _____; Woreda: _____; Kebele: _____

	Will the sub-project or business plan:	yes	No
	Cause significant involuntary displacement of people or social disturbances, involuntary loss of assets? The Bank does not provide specific categorization criteria relating to OP 4.12, Involuntary Resettlement. Generally, projects with significant resettlement-related impacts would be classified as Category A. Application of judgment is necessary in assessing the potential significance of resettlement-related impacts, which vary in scope and scale from project to project. Projects that would require physical relocation of residents or businesses, as well as projects that would cause any individuals to lose more than 10 percent of their productive land area often are classified as Category A. Scale may also be a factor, even when the significance of impacts is relatively minor. Projects affecting whole communities or relatively large numbers of persons (for example, more than 1,000 in total) may warrant classification as Category A, especially for projects in which implementation capacity is likely to be weak.		
	disrupt the quality or quantity of water in a waterway shared with other nations		
	Cause degradation of critical natural habitats cause any loss of biodiversity? Cause any large-scale physical disturbance of the site or the surroundings The project is classified as Category A if the screening indicates the potential for significant conversion or degradation of critical or other natural habitats. *Significant conversion* is the elimination or severe diminution of the integrity of critical or other natural habitats caused by a major, long-term change in land use or water use. Significant conversion may include, for example, land clearing; replacement of natural vegetation; permanent flooding; drainage, dredging, filling, or channelization of wetlands; or surface mining. Conversion can result directly from the action of a project or through an indirect mechanism (e.g., through induced settlement along a road). *Degradation* is modification of a critical or other natural habitat that substantially reduces the habitat's ability to maintain viable population of native species.		
	affect important physical and cultural resources (historical, religious, archaeological sites and monuments) Physical Cultural Resources, as defined under OP 4.11, are movable or immovable objects, sites, structures, groups of structures, and natural features and landscapes that have archaeological, paleontological, historical, architectural, religious, aesthetic, or other cultural significance. A project that will likely have significant adverse impacts on PCR is classified as Category A.		
	affect any vulnerable or underserved groups The Bank does not provide specific categorization criteria relating to OP 4.10, Indigenous Peoples. Though the policy applies whenever a group meeting the Bank's definition of Indigenous Peoples is present in the project area, categorization typically reflects the potential significance of any adverse impacts upon such groups. Projects that would require relocation of Indigenous Peoples, that would restrict their access to traditional lands or resources, or that would seek to impose changes to Indigenous Peoples' traditional institutions, are always likely to be classified as Category A.		
	Implemented in or around non-viable community centers (CCs)		
	likely to use pesticides or other agro-chemicals Projects that include the manufacture, use, or disposal of environmentally significant quantities of pest control products are classified as Category A. Environmental significance takes into account the impacts, including		

benefits, on human health.		

Recommendations:

- Sub-project/business plan is not eligible and rejected: _____
- Sub-project/business plan is eligible and approved: _____

Name, telephone and signature of members who did the eligibility check
1_____
2_____
3_____

D. Annex 4: Checklist for environmental and social impact identification and rating

Environmental and Social Feature	Impact Rating				
Social Issues					
	None	low	medium	high	unknown
reduce other people access to their economic resources, like land, pasture, water, public services or other resources that they depend on					
interference with access routes for people, livestock and wildlife or traffic routing and flows					
Result in resettlement of individuals or families or require the acquisition of land (public or private, temporarily or permanently) for its development?					
Result in the temporary or permanent loss of crops, fruit trees and household infra-structure (such as granaries, outside toilets and kitchens, etc.)? Effect on historical, archaeological or cultural heritage site?					
Effect on historical, archaeological or cultural heritage site? Effect on vulnerable people and underserved groups (e.g., elderly poor pensioners, physically challenged, women, particularly head of households or widows, etc.) Living in the area?					
Environmental Issues					
Effect on river, lake and wetland ecology					
Effect on plant, livestock or fishery or any other aquatic biodiversity					
Effect on protected areas designated by government (national park, national reserve, world heritage site)					
Effect on soil and water (surface or ground water) contamination and pollution					
Effect on aesthetic attractiveness of the local landscape					
Effect on the surrounding background noise level					
result in emission of copious amounts of dust, hazardous fumes					

Generate solid and/or liquid wastes (including human excreta/sewage and/or/ livestock waste)					
Generate air pollutants and/or greenhouse gases					
Human Health Issues					
Occupational Health effects/ accidents and injuries to workers during construction or operation					
Health effects (communicable disease such as Malaria, TB, HIV/AIDS or non-communicable diseases –from toxic chemicals), Specify_____					

Recommendation

Approved without condition Partial ESIA required

Special plans would be prepared independently – mark [√] in the box below

ESMP RAP PMP Others (specify):

If the recommendation is to prepare ESMP or RAP or PMP or others, environmental and social assessment (initial environmental and social examination) is required by the implementing agency/proponent, and reviewed by the regulatory body.

Rejected

Reason for rejection

[Type here]

Completed by: [Name – type here]

Position: [type here]

Date: [type here]

E. Annex 5: Guideline for Monitoring and Evaluation of the implementation of ESMF

For the effective implementation of the ESMF a regular and period follow up is required. The objective of this is to:
-Alert project authorities by providing timely information about the success or otherwise of the environmental management process outlined in this ESMF. This will ensure continuous improvement to ICDSEP environmental and social management process during the life cycle of the project.
-Make a final evaluation in order to determine whether the mitigation measures incorporated in the technical designs and the ESMP have been successfully implemented.

Monitoring of Environmental and Social Indicators

The goals of monitoring are to:

- measure the success rate of the project;
- verify the accuracy of the environmental and social impact predictions;
- determine the effectiveness of measures to mitigate adverse effects of projects on the environment;
- determine whether interventions have resulted in dealing with negative impacts;
- determine whether further interventions are needed or monitoring is to be extended in some areas;

Monitoring indicators will be very much dependent on specific project contexts. Two opportunities will be taken to build a simple system for the monitoring and evaluation of environmental and social impacts:

Initial proposals
The key issues to be considered in the ICDSEP subprojects include monitoring of water quality, soil erosion, land degradation, vegetation removal, soil acidification and Stalinization, genetic biodiversity, anti-biotic resistance, wetland drainage, occupational health & safety for those working in animal health clinic/post and soil testing laboratory, health problem, agricultural production, pest management, land acquisition, income generation and livestock health care and population influx.
Monitoring and surveillance of subprojects will take place on a spot check basis. The spot checks consist of controlling the establishment of mitigation measures. It is not recommended to collect large amounts of data, but rather to base monitoring on observations to determine the trends in indicators.

Monitoring of participation process

The following are indicators for monitoring of the participation process involved in the project activities.

- Number and percentage of affected households consulted during the planning stage
- Levels of decision-making of affected people
- Level of understanding of project impacts and mitigation
- Effectiveness of local authorities to make decisions
- Frequency and quality of public meetings
- Degree of involvement of women and youth or disadvantaged groups in discussions

Monitoring of implementation of mitigation plans lists the recommended indicators for monitoring the implementation of mitigation measures.
Evaluation of Results

The evaluation of results of environmental and social mitigation can be carried out by comparing baseline data collected in the planning phases with targets and post-project situations. A number of indicators would be used in order to determine the status of affected people and their environment (land being used compared to before (for example, how many irrigation subprojects than before)
In order to assess whether these goals are met, the IAs at Woreda and regional level will indicate the following in the ESMP. The Woreda and regional Office responsible for environment, and the PAP-LDP regional ESS expert will review/check these issues
The regional and federal PAP-LDP safeguard specialist will give technical assistance for IAs in doing so. The following are some pertinent parameters and verifiable indicators/questions to be used to measure the ESMF process, mitigation plans and performance.

- Have the ICDSEP coordination units at federal and regional level in collaboration with the regional and Woreda office responsible for environment trained a local social and environmental specialist, and IAs focal person in charge of ICDSEP activities in considering the social and environmental issues?
- Have the ESMP's and final subproject designs been cleared by the office responsible for environment offices at Woreda and regional level ?
- At what rate are the IAs monitor ESMF implementations?
- How many RAPs/s have been fully executed before physical displacement of people?
- How many recorded grievance cases have been settled within one year?

Monitoring of ESMF implementation

In addition to the Project Reports and ESA studies required under the Ethiopian Environmental legislation, an Audit on ESMF implementation will be done every other year and report prepared by the Woreda office responsible for environment office for those projects executed by the Woreda IAs and delivered to its office. Again the regional office responsible for environment will conduct auditing for those PAP-LDP subprojects executed by the regional IAs. The audits conducted both at regional and Woreda level would be sent to the Ministry of Peace and Ministry of Environment, Forest and Climate (MEFCC). All implementing agencies would conduct their own regular internal ESMF implementation audit and submit to the office responsible for environment e at their respective level. The regional and federal PAP-LDP safeguard specialists facilitate and supervise the execution of the audit, and also provide technical support in doing so.

Monitoring Roles and Responsibilities

PAP-LDP coordination units and IAs at Woreda and regional level have the lead responsibility to monitor the implementation of the ESMP including the PMP and the RAP that they prepare. The office responsible for environment at the offices at Woreda and regional level have also the responsibility to verify the monitoring report prepared by the IAs at their respective level. The office responsible for environment at woreda level will be required to prepare periodic monitoring reports and submit it to regional Office responsible for environment where periodic monitoring report prepared and submitted to regional coordination unit of PAP-LDP to be compiled and submitted to FPCU. ESS specialists at Regional and federal PCUs will facilitate and provide technical supports for the monitoring activities to be done by the regional and Woreda IAs and the office responsible for environment. They also carry out their monitoring activity to track the progress of the implementation of the mitigation measures prepared Woreda and regional IAs/PCUs. Development agents (DAs), KDCs and local community have also the responsibility to follow up the implementation of the ESMF at their locality. Donor representatives, independent consultants, Woreda TC, Zone TC and IAs have a role of giving support for the monitoring program.

Supervision

Supervising the implementation of ESMPs, which include ESMP, PMP and RAP/, will be the responsibility of the office responsible for environment offices at Woreda and regional level? Environment and Social safeguard specialists at Regional and federal PCUs of PAP-LDP will provide technical supports, and facilitate the process. Supervision of the ESMPs covers monitoring, evaluative review and reporting. Generally, it is designed to:

- determine whether the subproject is being carried out in conformity with environmental safeguards and legal agreements,
- identify problems as they arise during implementation and recommend means to resolve them,
- recommend changes in project concept/design, as appropriate, as the project evolves or circumstances change and
- Identify the key risks to project sustainability and recommend appropriate risk management strategies.

It is vital that an appropriate environmental and social supervision plan by ESS experts in collaboration with environmental protection offices is developed with clear objectives to ensure the successful implementation of an ESMP.

F. Annex 6: Summary of Field assessment and stakeholder consultation

The EIA assessment team used different methods and techniques to assess environmental and social impacts of the ARIFP Project. The team discussed with different stakeholders including staff of the World Bank Country Office, Ethiopian Public Health Institute, Federal Ministry of Health and CDC Africa. Discussions were also held with different experts under various governmental institutions. This includes staffs from Federal Ministry of Health, Regional Health Bureau, Regional Public Health Laboratories, Zonal Health Offices and different hospitals including Hygiene and environmental Health Community Leaders, Regional & Zonal forest and environmental protection authority, Federal Forest, Environment and Climate Change Commission, Regional & Zonal Social & Labour affair, Water, Energy and Irrigation Bureau and Zonal Construction Office. Guided tours were also made to different government institutions such as, Ethiopian Public Health Institute, zonal hospitals, regional public health laboratories. In addition the team discussed with local community elders, Religious Leaders, local administration, Women & Youth Association and community members of the project area. The main objective of these visits were to get information on the current laboratory waste management practice, availability of laboratory equipment, specimen handling and transportation facilities.

The major findings of the field visit and public consultation from social and environmental point of view revealed that, the preconstruction, construction and operation phase of the project would have potential positive and negative impacts were presented in the following:-

- There will be destruction of some trees during site clearance;
- There will be slight pollution of air, soil and water;
- Temporarily loss of access to water, electricity or telephone services,
- noise and vibration disturbances;
- Obstruction of movement of people and vehicles;
- There will not be any displacement of people because the laboratory is going to be constructed within existing hospital;
- There is wetland and Small River in one of the sites so, Due care would therefore be taken on this particular site during construction and operational phases of the project to protect the water source from pollution.
- There are rivers 3.5 km away from Humera site, Shebele river 1.5 KM from Gode site, Baro river 3km far from Gambella site, Tsebel river 8 km away from Ghinir site, seasonal river 2km far from Assossa site.
- During the field visit liquid and solid waste management practice on these sites were also investigated by the team. In most cases waste from these hospitals are discharged to a centralized septic tank before it is collected by municipality of the cities and discharged into the surrounding environment.
- Existing waste management practices are solid wastes including sharp materials are burned in an incinerator, placenta buried in a designated placenta pits and expired medicines and drugs are buried in concrete wall within the premise of the hospital;
- Improving community health;
- Create job opportunities for local community;

G. Annex 7 . An indicative Terms of Reference for Environmental and Social Audit Consultant

Project title: Africa CDC Regional Investment Financing Program

I. Background of the Project

The Africa CDC project is divided into three components; (a) Africa CDC headquarters; (b) support to Ethiopia; and (c) support to Zambia. Each component has four sub components including: (i) regulatory framework; (ii) public health assets (which includes laboratories, surveillance networks, and response networks); (iii) human resource development; and (iv) project management and execution. The project proposes to place as much emphasis on surveillance, response systems, and sustainability, as the construction and fitting out of laboratories.

Ethiopia has a three-tiered national reference laboratory system with the national reference laboratory serving as the hub. At present, there are some 35 laboratories throughout the country, but their facilities are, generally, inadequate for the scope of services proposed by the project and quality varies significantly among them. Ethiopian Public Health Institute (EPHI) proposes to construct a new (BSL3) laboratory adjacent to its offices in Addis Ababa in addition to equipping 15 newly constructed laboratories which are in border regions of neighboring fragile states and 8 BSL 2 laboratories constructed by GF. It also proposes to construct additional laboratories which will ramp up microbiology testing capacity throughout the country, provide the much-needed capacity for testing for zoonotic diseases, and provide services which are capable of virological diagnosis. The regional laboratories will be networked within Ethiopia as well as with cross-border neighbouring laboratories and health systems, many of which are in fragile states with weak detection capabilities.

This environmental and social audit is therefore intended to assess environmental information about the BSL 2 laboratories which will be financed by Africa CDC, to verify whether, or to what extent, the regional laboratories conform to specified environmental and social audit criteria stipulated in the audit protocol which is based on local, national or international environmental standards, national laws and regulations and guidelines of the World Bank.

II. Scope of the Work

The consultant would perform the following major tasks to fulfil the objectives of the consultancy service:

Task 1: Environmental legislation review. A review of relevant environmental and occupational health and safety legislations in the Federal Democratic Republic of Ethiopia and the World Bank. Verify compliance with Ethiopian laws and regulations, World Bank guidelines or accepted international standards for all important environmental impacts. To this end:

- Review relevant existing environmental legislation, standards, and permits.

- Evaluate knowledge and awareness of, and responsibility for, applicable legislation in BSL 2 laboratories which will be financed by Africa CDC.
- Examine compliance record with the BSL 2 laboratories' management
- Examine monitoring programs, procedures and controls in place in BSL 2 laboratories which will be financed by Africa CDC.
- Examine procedures for corrective action if monitoring parameters are out of control limits.
- Examine ifsuch incidents are reported, investigated, and followed up. Check if monitoring data are used for reporting to management or government agencies.
- Verify monitoring results or compliance by taking and analyzing representative samples.

Task 2: Site inspections and assessment. All 23 BSL 2 laboratories buildings and properties in which significant laboratory, or chemical storage/ disposal operations are conducted are to be included in the audit. Specific tasks under this include:

2.1 ***Assessment of significant risks including chemical use, waste management, risk of soil and ground water contamination, and fire and explosion risks***

- Examine areas for storage of dangerous substances, fuels, and gases. Check warning systems, fire fighting equipment, labeling of containers, spill protection, and compatibility of materials stored together.
- Assess procedures and controls in areas where dangerous processes occur.
- Check safety data sheets for spills and leakages, which would be available centrally and at all points of use.
- Evaluate adequacy of emergency procedures and contingency plans.
- Perform a tour of areas where practices of waste management, storage and the use of dangerous substances may have caused contamination.

2.2. Assessment of health and safety issues for both employees and the local community.

- Examine procedures and rules for employee protection and assess the level of compliance with company policies in the areas of noise, personal protective gear, hot work and other potentially harmful activities.
- Evaluate accident/incident reporting, analysis, and follow-up.
- Check if medical examinations for employees working in areas where they may be exposed to dangerous substances are available. Check if particular symptoms or diseases are monitored.
- Examine the existence of asbestos in buildings and equipment and procedures for dealing with asbestos.
- Evaluate the adequacy of training and emergency drills for employees.
- Examine record of complaints from the local community and systems to follow these up.
- Assess hazards or risks for the local community and the adequacy of procedures for warning and emergency responses.

2.3. Assess adequacy of internal controls, management procedures and practices for dealing with the environmental, safety and health issues at hand.

- Assess management awareness and commitment to environmental issues in the fifteen regional laboratories which will be financed by Africa CDC and 8 BSL 2 laboratories constructed by GF (which will be equipped by Africa CDC Project)
- Evaluate adequacy and clarity of policies, objectives, targets and plans in the context of legislative requirements.
- Evaluate how well environmental goals are communicated, understood and implemented in the BSL 2 laboratories.
- Examine responsibilities for environmental laws and regulations and the communication process with enforcement agencies in the BSL 2 laboratories.
- Evaluate the roles and responsibilities for environmental management functions.
- Assess document control procedures and the quality and use of records, procedures, registers and instructions in the BSL 2 laboratories.
- Examine feedback mechanisms in the form of corrective action systems, audit procedures and management reviews in the BSL 2 laboratories.

III. Output /deliverable of the consultancy service

An Environmental and Social Audit report with recommended time-bound action plan

IV. Duration of the assignment

The consultant is expected to deliver the final report within 25 days.

IV. Qualification requirements

The environmental and social audit consultants would be familiar with laws and regulations of national EIA, technical standards and requirements related to environmental audit, with experience in environmental audit. The consultants would have at least master's degree in Environmental Science or related fields and would have at least 10 years relevant experience.

H. Annex 8: Audit Checklist for BSL 2 laboratories to be financed by Africa CDC Program in Ethiopia

Instruction

The audit report will include:

- An executive summary (This would highlight the key findings, the remaining unknowns, and a statement summarizing the consultant's main conclusions relating to environmental and occupational health and safety practices at the Ethiopian Public Health Institute Laboratory
- Review of relevant environmental and occupational health and safety legislations
- Environmental and occupational health and safety concerns associated with the BSL 2 laboratories;
- Prioritization of all past and ongoing concerns (i.e. high, medium, and low);
- Recommendations (recommend what further action is required along with a cost estimate for such actions for both past and ongoing activities. Recommendations and cost estimates would be presented separately for past and ongoing activities, and in relation to both Ethiopian and the World Bank standards)

Table: Checklist of relevant audit activities for BSL 2 laboratories to be financed by Africa CDC Program in Ethiopia

S.N	Specific criteria	Compliance/Conformity		
		Yes	No	Remark
1	**The laboratory's compliance with management of risks associated with chemical use and storage, medical /infectious waste management, and fire and explosion risks**			
1.1	Does the laboratory have a system to receive infectious materials in a safe condition?			
1.2	Are the laboratory workers trained on safe handling of infectious substances according to Ethiopian and/or international regulations?			
1.3	Are infectious materials placed in biological safety cabinets with care and attention to the likely breakage and leakage?			
1.4	Are discarded infectious materials disposed of safely?			
1.5	Are the laboratory workers aware of procedures for dealing with spillage of infectious materials?			
1.6	Do the laboratory workers check the performance of sterilizers using chemical, physical and biological indicators?			
1.7	Have there been an appropriate use of disinfectants in the lab? Are the disinfectants in use suitable?			
1.8	Have the laboratory workers been provided with glove and other protective clothing?			

S.N	Specific criteria	Compliance/Conformity		
		Yes	No	Remark
1.9	Have there been an appropriate laboratory chemical labelling and warning practice?			
1.20	Are flammable chemicals safely stored in approved cabinets?			
1.21	Are the laboratory workers trained on how to deal with spills; how to safely work with radioactive materials and provided with spill skits?			
1.21	Are there warning systems, fire fighting equipment, labeling of containers, spill protection, and care in compatibility of materials stored together?			
1.22	Have there been practices to store flammable laboratory chemical in proper ventilated containers that are non-combustible?			
1.23	Does the laboratory have appropriate fire extinguishers and/or fire blankets?			
1.24	Does the laboratory have a practice to store flammable substances in appropriately constructed flammable storage cabinets?			
1.25	Is there a procedure to identify the potential for and respond to accidents and emergencies?			
1.26	Is there a procedure to mitigate impacts of accidents and emergencies?			
1.27	Is the emergency procedure, if any, tested?			
1.28	Are laboratory rooms equipped with fire extinguishers and/or fire blankets for emergency use, where appropriate?			
2	**The laboratory's compliance with pertinent Ethiopian laws and regulations, World Bank safeguards policies and WBG EHS guidelines or accepted international standards for all important environmental impacts**			
2.1	Have laboratory safety manual/regulation been prepared based on the ESMF /ESIA and pertinent laws and guidelines?			
2.2	Does the laboratory regulation/safety manual include commitments to prevention of pollution and comply with environmental requirements?			
2.3	Has the laboratory safety manual/regulation been, implemented, maintained and communicated to all laboratory workers?			
2.4	Is the laboratory's safety manual/ regulation, if any, appropriate to its activities and potential environmental impacts?			
2.5	Do the laboratory workers and management have knowledge and awareness of, and responsibility for, applicable environment, health and safety legislations?			
2.6	Does the laboratory have appropriate compliance record and documentation (to be checked with management and with relevant government authorities)			
2.7	Does the laboratory have appropriate monitoring system, procedures and controls in place?			
2.8	Is the monitoring data reliable (by evaluating monitoring design, sampling strategy, and control procedures)?			
3	**The laboratory's compliance with health and safety issues for both employees and the local community**			
3.1	Is there a procedure and rule for laboratory workers protection from work related hazards?			

S.N	Specific criteria	Compliance/Conformity		
		Yes	No	Remark
3.2	Has the laboratory been complying with the rule indicated in 3.1, if any?			
3.3	Does the laboratory have an accident/incident reporting, analysis, and follow-up system?			
3.4	Is there a practice of medical examinations for laboratory workers who may be exposed to dangerous substances?			
3.5	Has the laboratory placed an adequate procedure to avoid hazards or risks for the local community? Is there adequate procedure for warning and emergency responses?			
3.5	Is there a procedure to record of complaints from the local community and systems to address and follow these up?			
3.6	Have laboratory workers been provided appropriate protective clothing such as gowns, gloves?			
3.7	Is there emergency shower facility?			
3.8	Does the laboratory have radiation protection in accordance with national and international standards?			
3.9	Have training been provided to the laboratory staff so that they could follow appropriate biosafety practices?			
3.10	Are there first-aid boxes at appropriate locations in the laboratory?			
3.11	Have there been an immunization practice pertinent to the work of the laboratory?			
3.12	Does the lab encourage workers to report potential exposures to hazards?			
4	**Adequacy of the Laboratory's internal controls, management procedures and practices for dealing with the environmental, safety and health issues at hand**			
4.1	Do the laboratory staff and management have awareness and commitment to environmental issues?			
4.2	Is there an appropriate procedure in the lab to communicate and implement environmental goals?			
4.3	Has the laboratory clearly defined roles & responsibilities for environmental management?			

S.N	Specific criteria	Compliance/Conformity		
		Yes	No	Remark
4.4	Is there an appropriate documentation /records in the lab records to track performance and compliance with environmental management regulations and instruments?			
4.5	Does the lab have internal environmental audit procedure?			
4.6	Does lab management conduct periodic environmental performance reviews and take corrective measures as appropriate?			
4.7	Is there a feedback mechanism in the form of corrective action systems?			
4.8	Does the lab have established a procedure for handling, investigating and controlling, and mitigating non-compliance?			

I. Annex 9 Protocol for transportation of infectious substances

Introduction

Infectious substances are transported for a variety of different reasons, within countries and across international borders. It is obligatory upon shippers to ensure packaging and shipping conditions meet regulatory requirements to preserve the integrity of materials and facilitate their timely arrival at destination. The protocol provides information for classifying infectious substances for transportation and ensuring their safe packaging. They stress the importance of developing a working relationship between those involved – the sender, the carrier and the receiver – in order to provide for safe and expeditious transport of these materials. This Protocol provides practical guidance to facilitate compliance with applicable international regulations for the transport of infectious substances and patient specimens by all modes of transport, both nationally and internationally. It is adopted from WHO Guidance on regulations for the transport of infectious substances 2015–2016.

General preparation of shipments for transport

Because of the differences in the hazards posed by Category A infectious substances (UN 2814 and UN 2900) and Category B infectious substances (UN 3373), there are variations in the packaging, labelling and documentation requirements for the two categories. The packaging requirements are determined by UNCETDG and are set out as Packing Instructions P620 and P650, reproduced. The requirements are subject to change and regular upgrade by the organizations mentioned.

The current packaging requirements are described below.

Note 1: Hand carriage of Category A and Category B infectious substances and transport of these materials in diplomatic pouches are strictly prohibited by international air carriers.

Note 2: Inner packaging containing infectious substances shall not be consolidated with inner packagings containing unrelated types of goods.

Shippers of infectious substances shall ensure that packages are prepared in such a manner that they arrive at their destination in good condition and present no hazard to persons or animals during transport.

Basic triple packaging system

This system of packaging shall be used for all infectious substances. It consists of three layers as follows:

- **Primary receptacle**. A primary watertight, leak-proof receptacle containing the specimen. The receptacle is packaged with enough absorbent material to absorb all fluid in case of breakage or leakage.
- **Secondary packaging.** A second durable, watertight, leak-proof packaging to enclose and protect the primary receptacle(s). Several cushioned primary receptacles may be placed in one secondary packaging, but sufficient additional absorbent material shall be used to absorb all fluid in case of breakage or leakage.

- **Outer packaging.** Secondary packaging are placed in outer shipping packaging with suitable cushioning material. Outer packaging protect their contents from outside influences, such as physical damage, while in transit. The smallest overall external dimension shall be 10 x 10 cm.

Each completed package is normally required to be correctly marked, labelled and accompanied with appropriate shipping documents (as applicable). The requirements for these aspects are described below.

Packaging, labelling and documentation requirements for infectious substances in Category A Packaging

An infectious substance category A which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.

Infectious substances in Category A may only be transported in packaging that meets the United Nations class 6.2 specifications and complies with Packing Instruction P620 (see Annex 3; Figure 1). This ensures that strict performance criteria are met; tests for compliance with these criteria include a 9-metre drop test, a puncture test, a pressure test and a stacking test. The outer packaging shall bear the United Nations packaging specification marking (Figure 2), which indicates that the packaging has passed the performance tests to the satisfaction of the competent authority.

The primary receptacle or the secondary packaging shall be capable of withstanding a pressure differential of not less than 95 kPa. The United Nations packaging specification marking alone does not indicate that a test for this has been undertaken, and packaging users should ask their suppliers whether the completed package meets this requirement. There is no comprehensive list of suppliers of packaging that comply with Packing Instruction P620. However, an Internet search using a suitable international or national search engine usually provides appropriate information, as well as access to national regulations. Search phrases such as “UN packaging” and “UN infectious substance packaging” produce extensive results. Carriers and forwarding agents should also be able to supply details of local suppliers or local companies that can provide such information.

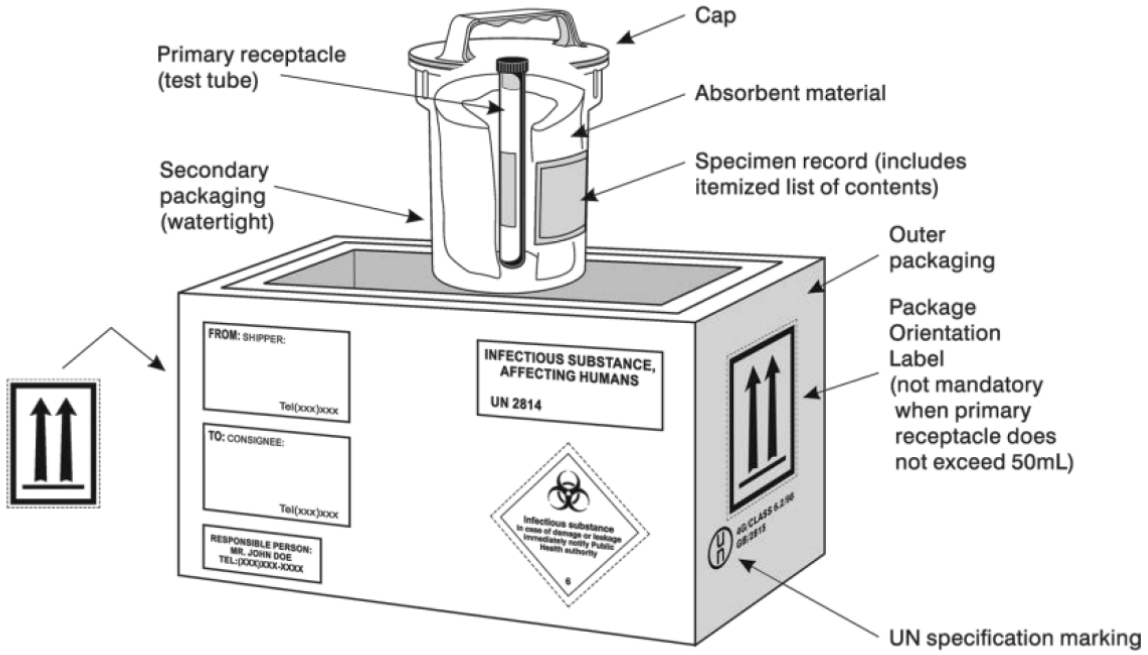


Figure 1. Example of triple packaging system for the packaging and labelling of Category A infectious substances

Marking

Packages are marked to provide information about the contents of the package, the nature of the hazard, and the packaging standards applied. All markings on packages or overpacks shall be placed in such a way that they are clearly visible and not covered by any other label or marking. Each package shall display the following information on the outer packaging or the overpack.

- the shipper's (sender's, consignor's) name and address
- the telephone number of a responsible person, knowledgeable about the shipment
- the receiver's (consignee's) name and address
- the United Nations number followed by the proper shipping name (UN 2814 "INFECTIOUS SUBSTANCE, AFFECTING HUMANS" or UN 2900 "INFECTIOUS SUBSTANCE, AFFECTING ANIMALS only", as appropriate). Technical names need not be shown on the package.
- temperature storage requirements (optional)
- when dry ice or liquid nitrogen is used: the technical name of the refrigerant, the appropriate United Nations number, and the net quantity.

Labelling

There are two types of labels:

1. hazard labels in the form of a square set at an angle of 45° (diamond- shaped) are required for most dangerous goods in all classes;

2. handling labels in various shapes are required, either alone or in addition to hazard labels, for some dangerous goods. Specific hazard label(s) shall be affixed to the outside of each package for all dangerous goods to be shipped (unless specifically exempted).

Figure 2. Hazard label for Category A infectious substances and for genetically modified microorganisms and organisms that meet the definition of an infectious substance, Category A

Minimum dimensions: 100 × 100 mm (for small packages: 50 × 50 mm) No. of labels per package: 1 Colour: Black and white The words “INFECTIOUS SUBSTANCE” shall be shown. The statement “In case of damage or leakage immediately notify a Public Health Authority” is required in some countries

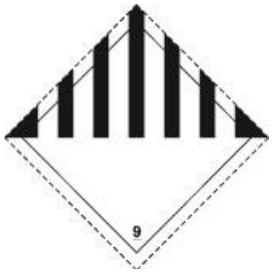
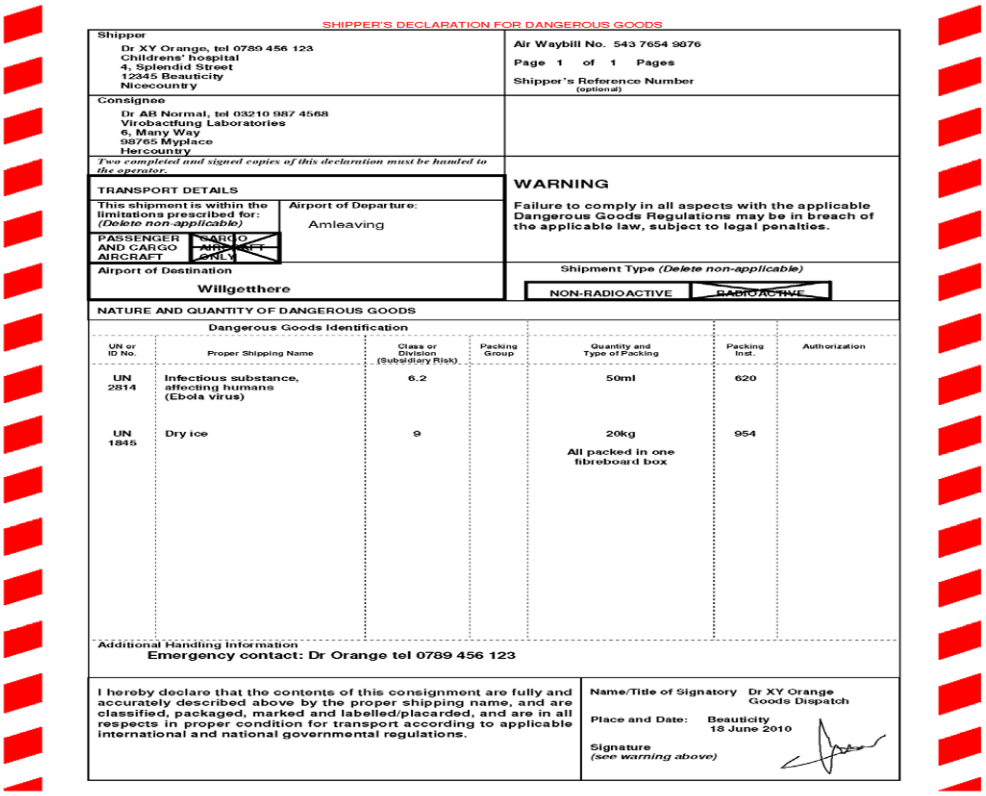


Figure 3 . Hazard label for certain noninfectious genetically modified microorganisms and organisms (UN 3245) and for carbon dioxide, solid (dry ice) (UN 1845); substances packed in dry ice (see section on Refrigerants) shall bear this label in addition to the primary risk label (e.g. the label shown in

Shipping empty packaging’

Before an empty package is returned to the shipper, or sent elsewhere, it must be appropriately disinfected or sterilized to nullify any hazard. Any label or marking indicating that it had contained an infectious substance shall be removed or covered.



SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper
Dr XY Orange, tel 0789 456 123
Childrens' hospital
4, Splendid Street
12345 Beauticity
Nicecountry

Air Waybill No. 543 7654 9876
Page 1 of 1 Pages
Shipper's Reference Number (optional)

Consignee
Dr AB Normal, tel 03210 987 4568
Virobactfung Laboratories
6, Many Way
98765 Myplace
Hercountry

Two completed and signed copies of this declaration must be handed to the operator.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for: *(Delete non-applicable)*
PASSENGER AND CARGO AIRCRAFT / CARGO AIRCRAFT ONLY

Airport of Departure: Amleaving

Airport of Destination: Willgetthere

WARNING

Failure to comply in all aspects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

Shipment Type *(Delete non-applicable)*
NON-RADIOACTIVE / ~~RADIOACTIVE~~

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification

UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Inst.	Authorization
UN 2814	Infectious substance, affecting humans (Ebola virus)	6.2		50ml	620	
UN 1845	Dry ice	9		20kg All packed in one fibreboard box	954	

Additional Handling Information
Emergency contact: Dr Orange tel 0789 456 123

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

Name/Title of Signatory Dr XY Orange
Goods Dispatch
Place and Date: Beauticity 18 June 2010
Signature *(see warning above)*

Figure 4. Example of a completed shipper's Declaration for Dangerous Goods

Packaging, labelling and documentation requirements for infectious substances in Category B Packaging

Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373

The triple packaging system continues to apply, including for local surface transport. Testing documents are not required, however. It may be possible to source packagings locally rather than finding an authorized supplier, provided that the packaging manufacturer and the shipper can comply fully with the requirements of P650 . As for P620, there is no comprehensive list of suppliers of packagings that comply with Packing Instruction P650. However, an Internet search using a suitable international or national search engine usually provides appropriate information, as well as access to national regulations. Search phrases such as "UN packaging" and "UN infectious substance packaging" produce extensive results. Carriers and forwarding agents should also be able to supply details of local suppliers or local companies that can provide such information.

To ensure correct preparation for transport, packaging manufacturers and subsequent distributors shall provide clear instructions to the consignor or persons preparing packages (e.g. patients) on how the packaging should be filled and closed.

For surface transport there is no maximum quantity per package.

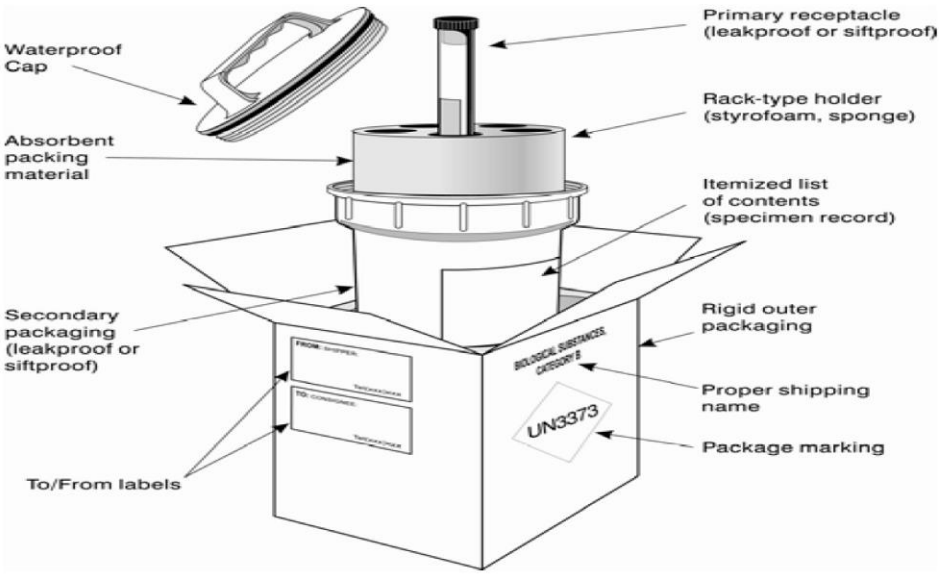


Figure 5: Example of the triple packaging system for the packing and labelling Category B infectious substances (adopted from WHO)

For air transport:

- no primary receptacle shall exceed 1 litre and the outer packaging must not contain more than 4 litres(for liquids)
- except for packages containing body parts, organs or whole bodies, the outer packaging must not contain more than 4 kg (for solids).

Provided all the requirements of P650 are met, there are no other transport requirements. P650 incorporates all that is needed to make a shipment for Category B infectious substances.

Marking

Each package shall display the following information:

- for air: the shipper's (sender's, consignor's) name, address and telephone number
- for air: the telephone number of a responsible person, knowledgeable about the shipment
- the receiver's (consignee's) name, address and telephone number
- the proper shipping name ("BIOLOGICAL SUBSTANCE, CATEGORY B") adjacent to the diamond-shaped mark shown in Figure 10
- temperature storage requirements (optional).

The marking shown in Figure 10 is used for shipments of Category B infectious substances.

Figure 6. Marking for infectious substances of Category B

- Minimum dimension: the width of the line forming the square shall be at least 2 mm, and the letters and numbers shall be at least 6 mm high. For air transport, each side of the square shall have a length of at least 50 mm
- Colour: none specified, provided the mark is displayed on the external surface of the outer packaging on a background of contrasting colour and that it is clearly visible and legible
- The words “BIOLOGICAL SUBSTANCE, CATEGORY B” in letters at least 6 mm high shall be displayed adjacent to the mark.

Note: For air transport:

- when dry ice (solid carbon dioxide) is used (see section on Refrigerants), the label shown in Figure 4 shall be applied
- for cryogenic liquids (see section on Refrigerants) the labels shown in Figures 5 and 6 shall also be affixed.

Documentation

Dangerous goods documentation (including a shipper’s declaration) is not required for Category B infectious substances. The following shipping documents are required. To be prepared and signed by the shipper (sender, consignor):

- for international shipments: a packing list/proforma invoice that includes the shipper's and the receiver’s address, the number of packages, detail of contents, weight, value (Note: the statement “no commercial value” shall appear if the items are supplied free of charge)
- an import and/or export permit and/or declaration if required.

To be prepared by the shipper or the shipper’s agent:

- an air waybill for air transport or equivalent documents for road, rail and sea journeys.

Refrigerants

Refrigerants may be used to stabilize infectious substances in Categories A and B during transit.

- Packed infectious substances requiring cooling assigned to packing instructions P620 or P650 shall meet the appropriate requirements of that packing instruction.
- Ice, ice pads or dry ice shall be placed outside the secondary receptacle or in an outer packaging or in an overpack.
- Wet ice shall be placed in a leak-proof container; the outer packaging or overpack shall also be leak-proof.
- Dry ice must not be placed inside the primary or secondary receptacle because of the risk of explosions. A specially designed insulated packaging may be used to contain dry ice. The packaging must permit the release of carbon dioxide gas if dry ice is used. Packing instruction P003 (ICAO/IATA PI954) shall be observed.
- The secondary receptacle shall be secured within the outer package to maintain the original orientation of the inner packages after the refrigerant has melted or dissipated.
- If dry ice is used to ship infectious substances in Category A, the details shall appear on the shipper's Declaration for Dangerous Goods. If dry ice is used to ship infectious substances in Category B or Exempt samples, the shipper's Declaration of Dangerous Goods is not required. In any case, the outermost packaging shall carry the hazard label for dry ice (see Figure 4), the appropriate markings, including the UN number and the proper shipping name followed by the words "AS COOLANT", *for example: UN 1845, CARBON DIOXIDE,SOLID, AS COOLANT*. and an indication of the net quantity of dry ice in kilograms.
- If liquid nitrogen is used as a refrigerant, special arrangements shall be made in advance with the carrier. Primary receptacles shall be capable of withstanding extremely low temperatures, and packaging and documentation requirements for liquid nitrogen shall be observed. In particular, the outermost packaging shall carry the hazard label for liquid nitrogen (see Figure 5). For air transport, the handling label for cryogenic liquids shall also be affixed (see Figure 6) – this is not considered further in these guidelines.
- When shipping with liquid nitrogen, "dry shippers" can be used. Correctly prepared "dry shippers" do not contain free liquid nitrogen. While liquid nitrogen is a regulated dangerous good, a properly prepared "dry shipper" is not. When shipping with "dry shippers", the dangerous goods label for class 2 (non-flammable, non-toxic gases) is NOT required. Shippers must properly mark and label the outside of dry shipper packages containing infectious substances. Appropriate documentation should discuss the presence of infectious substances. For Category A this information will be included in the Dangerous Goods Declaration. For Category B and Exempt packages this information should be provided on the Air Waybill.

Training

The dangerous goods regulations require all personnel involved in transport to undergo appropriate training. For the transport of Category A infectious substances, personnel must undergo training in

accordance with the modal requirements. This can involve attendance at approved courses and passing examinations. For the transport of Category B infectious substances there is a requirement that clear instructions on the use of the packaging are supplied to the user; this is regarded as sufficient "training" for the shipping of these substances. However, if such specimens are consigned with other dangerous goods (e.g. flammable liquids, radioactive materials, liquefied gases, etc.), then personnel must be trained in the proper procedures for their transport. Training and awareness are important for all personnel involved in the transport of Category B infectious substances. Training of personnel, for example via consultation of guidance documents like this one, while not formally required by the modal regulations, is recommended and encouraged. Only through appropriate guidance and training can shippers ensure that the classification of the substance to be shipped is correct, and that proper packaging is selected and prepared. Carriers and other employers of transport workers should train their personnel in the appropriate procedures for recognizing and handling packages containing infectious substances and in how to address spills and protect themselves from exposure.

Records of training received shall be kept by the employer and made available to the employee or competent authority, upon request. Records shall be kept by the employer for a period of time established by the competent authority.

Transport planning

It is the responsibility of the shipper to ensure the correct classification, packaging, labelling, and documentation of all infectious substances destined for transport. The efficient transport and transfer of infectious substances requires good coordination between the sender, the carrier and the receiver to ensure that the material is transported safely and arrives on time and in good condition. Such coordination depends upon well-established communications and a good working relationship between the three parties.

The carriage of any goods whether dangerous or not, is a commercial matter for a carrier. The dangerous goods rules described in these guidelines reflect governmental legal requirements. Indeed, different countries may have adopted State variations to the United Nations Model Regulations. In addition, a carrier that does not wish to carry particular goods is under no legal obligation to do so. Many carriers (airlines, haulers and shipping lines) are "private carriers" and have the right to refuse to carry goods or add additional requirements. In recent years it has become clear that some carriers are indeed refusing to carry certain goods or are adding extra conditions. Provided such conditions do not conflict with the legal requirements, this type of action is not illegal.

ICAO and IATA list the main carrier restrictions in force among airlines. Some airlines will not carry dangerous goods at all, while others will carry only a very limited range of goods. As carrier restrictions for the different modes of transport are not published centrally, harmonization between stakeholders is essential. The shipper (sender, consignor), carrier and the receiver (consignee) have specific responsibilities in ensuring successful transportation.

The shipper (sender, consignor)

• Makes advance arrangements with the receiver including investigating the need for import/export permits

• Makes advance arrangements with the carrier to ensure: o that the shipment will be accepted for appropriate transport

o that the shipment (direct transport if possible) is undertaken by the most direct routing

• Prepares necessary documentation, including permits, dispatch and shipping documents

• Notifies the receiver of transportation arrangements once these have been made, well in advance of the expected arrival time.

The carrier

• Provides advice to the sender regarding the necessary shipping documents and instructions for their completion

• Provides advice to the sender about correct packaging

• Assists the sender in arranging the most direct routing and then confirms the routing

• Maintains and archives the documentation for shipment and transport.

The receiver (consignee)

• Obtains the necessary authorization(s) from national authorities for the importation of the material

• Provides the sender with the required import permit(s), letter(s) of authorization, or other document(s) required by the national authorities

• Arranges for the most timely and efficient collection on arrival

• Should acknowledge receipt to the sender.

Shipments should not be dispatched until:

• Advance arrangements have been made between the sender, carrier and receiver

• The shipper has confirmed with the national authorities that the material may be legally exported

• The receiver has confirmed with the national authorities that the material may be legally imported

• The receiver has confirmed that there will be no delay incurred in the delivery of the package to its destination.

Requirements for air mail

Infectious substances in Category A will not be accepted for shipment through postal services. Infectious substances in Category B may be shipped by registered air mail, and the Universal Postal Union recommends the following procedure. The basic triple packaging system is used with the same

requirements as for other means of transport. The address label shall display the word *"Lettre"* or "Letter" and the green Customs Declaration Label for Postal Mail is required for international mailing. "BIOLOGICAL SUBSTANCE, CATEGORY B" shall be identified with the white diamond label with black letters "UN 3373" (see Figure 10). Local/international restrictions may be in force. Prior contact should therefore be made with the national public operator to ascertain whether the packaged material will be accepted by the postal service in question.

Spill clean-up procedure

The appropriate response in the event of exposure to any infectious substance is to wash or disinfect the affected area as soon as possible, regardless of the agent. Even if an infectious substance comes into contact with non-intact skin, washing of the affected area with soap and water or with an antiseptic solution can reduce the risk of infection. Medical advice should be obtained any time there is a suspected exposure to infectious substances resulting from a damaged package. The following procedure for clean-up can be used for spills of all infectious substances including blood. The person must be trained on such procedure before performing these steps:

1. Wear gloves and protecting clothing, including face and eye protection if indicated.
2. Cover the spill with a cloth or paper towels to contain it.
3. Pour an appropriate disinfectant over the cloth or paper towels and the immediately surrounding area (5% bleach solutions are generally appropriate, but for spills on aircraft, quaternary ammonium disinfectants should be used).

4. Apply the disinfectant concentrically beginning at the outer margin of the spill area, working towards the centre.

5. After about 30 min, clear away the materials. If there is broken glass or other sharps are involved, use a dustpan or a piece of stiff cardboard to collect the materials and deposit them into a puncture-resistant container for disposal.

6. Clean and disinfect the area of the spillage (if necessary, repeat steps 2–5).

7. Dispose of contaminated materials into a leak-proof, puncture-resistant waste disposal container.

8. After successful disinfection, report the incident to the competent authority and inform them that the site has been decontaminated (see Incident reporting below).

Incident reporting

No reports of infections resulting from transport-related exposures have been documented other than the anthrax letters of 2001 in the USA. There have been reports of the transmission of acute respiratory infections and tuberculosis associated with air travel, but these were attributed to direct person-to- person contact and not to packaging problems or shipping incidents.

Statistical data collected by a group of central laboratories showed the efficacy of packaging compliant with P650 and P620 in assuring that infectious substances are transported without leakage and loss of

materials. For the 4.92 million primary containers shipped in 2003 to any of the worldwide regional offices of these central laboratories, just 106 breakages, 0.002% of the total number, were recorded. Moreover, the leakages that did occur were all contained by the absorbent material, and no damage to secondary containers or outer packaging was reported. The various international modal regulations require the reporting of incidents to the relevant competent transport authorities in addition to the necessary health authorities. This applies to both categories of infectious substances, but particularly to those in Category A.

Transport planning

It is the responsibility of the shipper to ensure the correct classification, packaging, labelling, and documentation of all infectious substances destined for transport. The efficient transport and transfer of infectious substances requires good coordination between thesender, the carrier and the receiver to ensure that the material is transported safely and arrives on time and in good condition. Such coordination depends upon well-established communications and a good working relationship between the three parties.

The carriage of any goods whether dangerous or not, is a commercial matter for a carrier. The dangerous goods rules described in these guidelines reflect governmental legal requirements. Indeed, different countries may have adopted State variations to the United Nations Model Regulations. In addition, a carrier that does not wish to carry particular goods is under no legal obligation to do so. Many carriers (airlines, haulers and shipping lines) are “private carriers” and have the right to refuse to carry goods or add additional requirements. In recent years it has become clear that some carriers are indeed refusing to carry certain goods or are adding extra conditions. Provided such conditions do not conflict with the legal requirements, this type of action is not illegal.

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The shipper (sender, consignor)

• Makes advance arrangements with the receiver including investigating the need for import/export permits

• Makes advance arrangements with the carrier to ensure: o that the shipment will be accepted for appropriate transport

o that the shipment (direct transport if possible) is undertaken by the most direct routing

• Prepares necessary documentation, including permits, dispatch and shipping documents

• Notifies the receiver of transportation arrangements once these have been made, well in advance of the expected arrival time.

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• Provides advice to the sender regarding the necessary shipping documents and instructions for their completion

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5. Cover the spill with a cloth or paper towels to contain it.
6. Pour an appropriate disinfectant over the cloth or paper towels and the immediately surrounding area (5% bleach solutions are generally appropriate, but for spills on aircraft, quaternary ammonium disinfectants should be used).

4. Apply the disinfectant concentrically beginning at the outer margin of the spill area, working towards the centre.

5. After about 30 min, clear away the materials. If there is broken glass or other sharps are involved, use a dustpan or a piece of stiff cardboard to collect the materials and deposit them into a puncture-resistant container for disposal.

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7. Dispose of contaminated materials into a leak-proof, puncture-resistant waste disposal container.

8. After successful disinfection, report the incident to the competent authority and inform them that the site has been decontaminated (see Incident reporting below).

Incident reporting

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Statistical data collected by a group of central laboratories showed the efficacy of packaging compliant with P650 and P620 in assuring that infectious substances are transported without leakage and loss of materials. For the 4.92 million primary containers shipped in 2003 to any of the worldwide regional offices of these central laboratories, just 106 breakages, 0.002% of the total number, were recorded. Moreover, the leakages that did occur were all contained by the absorbent material, and no damage to secondary containers or outer packaging was reported. The various international modal regulations require the reporting of incidents to the relevant competent transport authorities in addition to the necessary health authorities. This applies to both categories of infectious substances, but particularly to those in Category A.

Transport planning

It is the responsibility of the shipper to ensure the correct classification, packaging, labelling, and documentation of all infectious substances destined for transport. The efficient transport and transfer of infectious substances requires good coordination between the sender, the carrier and the receiver to ensure that the material is transported safely and arrives on time and in good condition. Such coordination depends upon well-established communications and a good working relationship between the three parties. The carriage of any goods whether dangerous or not, is a commercial matter for a carrier. The dangerous goods rules described in these guidelines reflect governmental legal requirements. Indeed, different countries may have adopted State variations to the United Nations Model Regulations. In addition, a carrier that does not wish to carry particular goods is under no legal obligation to do so. Many carriers (airlines, haulers and shipping lines) are “private carriers” and have the right to refuse to carry goods or add additional requirements. In recent years it has become clear that some carriers are indeed refusing to carry certain goods or are adding extra conditions. Provided such conditions do not conflict with the legal requirements, this type of action is not illegal. ICAO and IATA list the main carrier restrictions in force among airlines. Some airlines will not carry dangerous goods at all, while others will carry only a very limited range of goods. As carrier restrictions for the different modes of transport are not published centrally, harmonization between stakeholders is essential. The shipper (sender, consignor), carrier and the receiver (consignee) have specific responsibilities in ensuring successful transportation.

The shipper (sender, consignor)

• Makes advance arrangements with the receiver including investigating the need for import/export permits

• Makes advance arrangements with the carrier to ensure:

o that the shipment will be accepted for appropriate transport

o that the shipment (direct transport if possible) is undertaken by the most direct routing

• Prepares necessary documentation, including permits, dispatch and shipping documents

• Notifies the receiver of transportation arrangements once these have been made, well in advance of the expected arrival time.

The carrier

• Provides advice to the sender regarding the necessary shipping documents and instructions for their completion

• Provides advice to the sender about correct packaging

• Assists the sender in arranging the most direct routing and then confirms the routing

• Maintains and archives the documentation for shipment and transport.

The receiver (consignee)

• Obtains the necessary authorization(s) from national authorities for the importation of the material

• Provides the sender with the required import permit(s), letter(s) of authorization, or other document(s) required by the national authorities

• Arranges for the most timely and efficient collection on arrival

• Should acknowledge receipt to the sender.

Shipments should not be dispatched until:

• Advance arrangements have been made between the sender, carrier and receiver

• The shipper has confirmed with the national authorities that the material may be legally exported

• The receiver has confirmed with the national authorities that the material may be legally imported

• The receiver has confirmed that there will be no delay incurred in the delivery of the package to its destination.

Packing Instruction P620

This instruction applies to UN 2814 and UN 2900.

Infectious substances in Category A and designated as UN 2814 or UN 2900 may only be transported in packaging that meets the United Nations class 6.2 specifications and complies with Packing Instruction P620, which is reproduced below. The various provisions mentioned are set out in the United Nations Model Regulations.

The following packagings are authorized provided the special packing provisions described below are met: Packagings meeting the requirements and approved accordingly consisting of:

A. Inner packagings comprising:

(i) leakproof primary receptacle(s);
(ii) a leakproof secondary packaging;
(iii) other than for solid infectious substances, an absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated so as to prevent contact between them;

B. (b) A rigid outer packaging.

1. Drums (1A1, 1A2, 1B1, 1B2, 1N1, 1N2, 1H1, 1H2, 1D, 1G); Boxes (4A, 4B, 4N, 4C1, 4C2, 4D, 4F, 4G, 4H1, 4H2); Jerricans (3A1, 3A2, 3B1, 3B2, 3H1, 3H2).
2. The smallest external dimension shall be not less than 100 mm (4 in). **Additional requirements:**

1. Inner packagings containing infectious substances shall not be consolidated with inner packagings containing unrelated types of goods. Complete packages may be overpacked in accordance with the provisions of 1.2.1 and 5.1.2; such an overpack may contain dry ice.
2. Other than for exceptional consignments, e.g. whole organs which require special packaging, the following additional requirements shall apply:

- Substances consigned at ambient temperatures or at a higher temperature. Primary receptacles shall be of glass, metal or plastics. Positive means of ensuring a leakproof seal shall be provided,
  e.g. a heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they shall be secured by positive means, e.g., tape, paraffin sealing tape or manufactured locking closure;

- Substances consigned refrigerated or frozen. Ice, dry ice or other refrigerant shall be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with 6.3.3. Interior supports shall be provided to secure secondary packaging(s) or packages in position after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack shall be leakproof. If dry ice is used, the outer packaging or overpack shall permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used;
- Substances consigned in liquid nitrogen. Plastics primary receptacles capable of withstanding very low temperature shall be used. The secondary packaging shall also be capable of withstanding very low temperatures, and in most cases will need to be fitted over the primary receptacle individually. Provisions for the consignment of liquid nitrogen shall also be fulfilled. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the liquid nitrogen;
- Lyophilized substances may also be transported in primary receptacles that are flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals.

3. Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging shall be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa and temperatures in the range -40 °C to +55 °C (-40 °F to +130 °F).
4. Other dangerous goods shall not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 ml or less of dangerous goods included in Classes 3 (flammable liquids), 8 (corrosive substances) or 9 (miscellaneous dangerous substances and articles, including environmentally hazardous substances) may be packed in each primary receptacle containing infectious substances. These small quantities of dangerous goods of Classes 3, 8 or 9 are not subject to any additional requirements of these Regulations when packed in accordance with this packing instruction.
5. Alternative packagings for the transport of animal material may be authorized by the competent authority in accordance with the provisions of 4.1.3.7.
6.

Packing Instruction P650

This packing instruction applies to UN 3373

The text of United Nations Packing Instruction P650, in use for the transport of infectious substances in category B assigned to UN 3373 by all surface modes of transport is reproduced below. The shaded text on the right hand side indicates the ICAO variations to these instructions that apply to the transport by air. The various provisions mentioned are set out in the United Nations Model Regulations.

1. The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including trans-shipment between cargo transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings shall be constructed and closed to prevent any loss of

contents that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity or pressure.

2. The packaging shall consist of at least three components:
   (a) a primary receptacle,
   (b) a secondary packaging, and
   (c) an outer packaging of which either the secondary or the outer packaging shall be rigid

3. Primary receptacles shall be packed in secondary packagings in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings shall be secured in outer packagings with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.
4. For transport, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The mark shall be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm; the width of the line shall be at least 2 mm and the letters and numbers shall be at least 6 mm high. The proper shipping name “BIOLOGICAL SUBSTANCE, CATEGORY B” in letters at least 6 mm high shall be marked on the outer packaging adjacent to the diamond-shaped mark.

5. At least one surface of the outer packaging must have a minimum dimension of 100 mm × 100 mm.
6. The completed package shall be capable of successfully passing the drop test in 6.3.5.3 as specified in .3.5.2 of these Regulations at a height of 1.2 m. Following the appropriate drop sequence, there shall be no leakage from the primary receptacle(s) which shall remain protected by absorbent material, when required, in the secondary packaging.
7. For liquid substances
   - The primary receptacle(s) shall be leakproof;
   - The secondary packaging shall be leakproof; and must not contain more than 1 litre;
   - If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them;
   - Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;
   - The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar). For air transportation in the range of -40 °C to +55 °C (-40 °F to +130 °F).
   - The outer package must not contain more than 4 litres. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold
8. For solid substances
   (a) The primary receptacle(s) shall be siftproof;
   (b) The secondary packaging shall be siftproof;
   (c) (c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.
   (d) (d) Except for packages containing body parts, organs or whole bodies, the outer package must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold

(e) (e) If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, shall be used.

9. Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen

(a) When dry ice or liquid nitrogen is used as a coolant, the requirements of 5.5.3 shall apply. When used, ice shall be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports shall be provided to secure the secondary packagings in the original position. If ice is used, the outside packaging or overpack shall be leakproof.

(b) (b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost.

10. When packages are placed in an overpack, the package markings required by this packing instruction shall either be clearly visible or be reproduced on the outside of the overpack.

11. Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Regulations.

12. (12) Clear instructions on filling and closing such packages shall be provided by packaging manufacturers and subsequent distributors to the consignor or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for transport.

13. (13) Other dangerous goods shall not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 ml or less of dangerous goods included in Classes 3 (flammable liquids), 8 (corrosives) or 9 (miscellaneous dangerous substances and articles, including environmentally hazardous substances) may be packed in each primary receptacle containing infectious substances. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction no other requirements in these Instructions need be met.

Requirements for air mail

Infectious substances in Category A will not be accepted for shipment through postal services.

Infectious substances in Category B may be shipped by registered air mail, and the Universal Postal Union recommends the following procedure.

The basic triple packaging system is used with the same requirements as for other means of transport. The address label shall display the word *"Lettre"* or "Letter" and the green Customs Declaration Label for Postal Mail is required for international mailing. "BIOLOGICAL SUBSTANCE, CATEGORY B" shall be identified with the white diamond label with black letters "UN 3373" (see Figure 10). Local/international restrictions may be in force. Prior contact should therefore be made with the national public operator to ascertain whether the packaged material will be accepted by the postal service in question.

Spill clean-up procedure

The appropriate response in the event of exposure to any infectious substance is to wash or disinfect the affected area as soon as possible, regardless of the agent. Even if an infectious substance comes into contact with non-intact skin, washing of the affected area with soap and water or with an antiseptic solution can reduce the risk of infection. Medical advice should be obtained any time there is a suspected exposure to infectious substances resulting from a damaged package. The following procedure for clean-up can be used for spills of all infectious substances including blood. The person must be trained on such procedure before performing these steps:

1. Wear gloves and protecting clothing, including face and eye protection if indicated.
2. Cover the spill with a cloth or paper towels to contain it.
3. Pour an appropriate disinfectant over the cloth or paper towels and the immediately surrounding area (5% bleach solutions are generally appropriate, but for spills on aircraft, quaternary ammonium disinfectants should be used).
4. Apply the disinfectant concentrically beginning at the outer margin of the spill area, working towards the centre.

5. After about 30 min, clear away the materials. If there is broken glass or other sharps are involved, use a dustpan or a piece of stiff cardboard to collect the materials and deposit them into a puncture-resistant container for disposal.
6. Clean and disinfect the area of the spillage (if necessary, repeat steps 2–5).
7. Dispose of contaminated materials into a leak-proof, puncture-resistant waste disposal container.
8. After successful disinfection, report the incident to the competent authority and inform them that the site has been decontaminated (see Incident reporting below).

Incident reporting

No reports of infections resulting from transport-related exposures have been documented other than the anthrax letters of 2001 in the USA. There have been reports of the transmission of acute respiratory infections and tuberculosis associated with air travel, but these were attributed to direct person-to- person contact and not to packaging problems or shipping incidents. Statistical data collected by a group of central laboratories showed the efficacy of packaging compliant with P650 and P620 in assuring that infectious substances are transported without leakage and loss of materials. For the 4.92 million primary containers shipped in 2003 to any of the worldwide regional offices of these central laboratories, just 106 breakages, 0.002% of the total number, were recorded. Moreover, the leakages that did occur were all contained by the absorbent material, and no damage to secondary containers or outer packagings was reported. The various international modal regulations require the reporting of incidents to the relevant competent transport authorities in addition to the necessary health authorities. This applies to both categories of infectious substances, but particularly to those in Category A.

J. Annex 10: Some Minutes of Community and Stakeholders Consultation

ብሄራዊ ክልላዊ
መንግስቲትግራይ
ቢሮ ሓልዋ ጥዕ ካሕሳይ ኣበራ ሆስፒታል
Ref ----------
ቁፅሪ ----------

The Government of the National Regional
State of Tigray, Bureau of Health
Kahsay Abera Ho Spital
Date----------
ዕለት ----------

ቃለ-ጉባኤ

በሁመራ ከተማ ካ/አ/ሆስፒታል ከሆስፒታልና የአከባቢው ማህበረሰብ የተደረገ ውይይት

በርእሰ ጉዳዩ እንደተጠቀሰ በፌደራል ጤና ጥበቃ ሚኒስቴር ከአለም ባንክ በሚገኝ የአለም ገንዘብ ድጋፍ ሊገነቡ ከታቀዱ 15 ሳባራቱሪዎች መካከል አንዱ በሁመራ ከተማ በሚገኘው የካህሳይ አበራ ሆስፒታል ቅጥር ግቢ ውስጥ መሆኑ ይታወቃል፤ በዚህም መሰረት የሳባራቱሪው ግንባታ የሚያስከትለውን /ሊያስከትል የሚችለውን የአከባቢና የህብረተሰብ ተፅዕኖ (ENVIRONMENTAL AND SOCIOL IMPACT ASSEESSMENT) ከፌደራል ጤና ጥበቃና ከኢትዮጵያ ሕብረተሠብ ጤና ኢኒስቲቲዩት በተሳኩ ባለሞያዎች ተከናውኗል።

በጸሀሠሣ ጥናት ወቅትም የሚከተሉት ዋናዋና ተግባራት ተከናውነዋል፦

1. ለግንባታ የተዘጋጀውን ቦታ እና ዙርያው መቃኘት
2. ከሚመለከታቸው ባለ አድራሻ አካላት ጋር እና ከሕብረተሠቡ ጋር ውይይት ማድረግ
3. በአከባቢው/በሆስፒታሉ የለውን የውሃና የሃይል አቅርቦት ማየት
4. በተዘጋጀው መጠይቅ መሰረት የሳባራቱሪ ግንባታ ፕሮጀክቱ በአከባቢና በሕብረተሰቡ ላይ ሊያስከትል የሚያስችለውን ተፅዕኖ መገምገም
5. ለግንባታ የተዘጋጀውን ቦታ ፎቶ ማንሳትና እንዲሁም በውይይቱ የተሳተፉ አካላት ስም ዝርዝር ከፈረማቸው ጋር መካተት በተከናወነው የዳሠሣ ጥናት መሰረት በሆስፒታሉ ቅጥር ግቢ ውስጥ በቂና ለግንባታ አመቺ የሆነ ቦታ እንዳለ መመልከት ተችሎዋል፤ በተጨማሪም የሆስፒታሉ ቅጥር በግንብ አጥር የተከለለ በመሆኑ ግንባታው ከማነኛውም በአከባቢው ከሚገኝ ሌላ ይዞታ ጋር ንክኪ አይኖርውም።። ሳባረቱሪው በሚገነባበት ወቅትም አሁን ያለውን የሆስፒታል ህንፃ እንደማይነካና እንዲሁም መደበኛ የሆስፒታሉ የህክምና አገልግሎት ላይ አኩል እንደማያስከትል ለመገንዘብ ተችሎዋል።። ከሞሃ አቅርቦት አንፃር ሆስፒታሉ ከከተማው ከሚሰራጨው ውሃ በተጨማሪ በቅጥር ግቢው ውስጥ በቂ ይጥልቅ ጉድንድ ውሃ አቅርቦት እንዳለ ተገንዝበናል፣የኤሌክትሪክ ሃይል አቅርቦት እንዳለ የመቆራረጥ ችግር በብዛት እንደማይከተዋል ከተከሰተም ሆስፒታሉ በቂ ሃይል ማመንጨትና ማቅረብ የሚችሉ ጀነራተሮች እንዳሉት ማየት ተችለዋል በተጨማሪም ለግንባታ የመያስችሉ ግብዓቶች /ብረት፣ ስሚንቶ፣ጠጠር ፣ አሸዋ...ወዘተ/ በአከባቢው በብዛት እንደሚመረቱና እንደሚገኙ መገንዘብ ተችለዋል፣ በአጠቃላይ በተደረገው ውይይት እና ከአከባቢ ምልከታ መሰረት የታቀደው የሳባራቱሪ ግንባታ ቢከናወን የጤናውን ዘርፍ ለማሳለል እጅግ የጎላ ሚና ይኖረዋል፣

Mengesha Setegne Sams

Community and Stakeholders Consultations Attendance Sheet for Environmental and Social Assessment for Construction of Reference Laboratories

Federal Democratic Republic of Ethiopia

Regions SNNP Zone Bench Maji

Woreda/Town Mizan Aman

Date of Consultation 19/04/2019

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Community and Stakeholders Consultations Attendance Sheet for Environmental and Social Assessment for Construction of Reference Laboratories

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Date of Consultation 26/4/2019

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K. Annex 11: Guidelines for Management of Each Class of HCW

Class 1: Non-risk HCW

- Class 1 non-risk HCW shall be placed in black containers.
- Containers should be placed in all rooms, wards, and in all public areas.
- All non-risk HCW not designated for recycling shall be collected with the other municipal waste.
- Non-contaminated items that are designated for recycling shall be packed in specific black containers marked “Non-contaminated plastic, to be recycled” or white containers marked “Non-contaminated glassware, to be recycled.”
- Non-risk health care waste should be disposed of similarly to domestic garbage and food waste (burning, municipal waste collection, land fill, etc).

Class 2: Clinical waste (non-sharp infectious waste)

- All class 2 clinical waste shall be placed in yellow polyethylene bags (minimum 300 micron gauge) marked “Danger! Hazardous medical waste” and indicated with the international biohazard symbol.
- Bags shall be sealed with appropriate adhesive tape, removed, and replaced immediately when they are no more than three-quarters full.
- If available, yellow bins or containers shall be used—they must be systematically disinfected in a solution of 0.5% of sodium hypochlorite or Lysol every time they are emptied.
- All class 2 clinical HCW shall be buried in a protected pit or incinerated in double-chamber incinerators.
- In highly densely populated areas, centralized pyrolytic incinerators reaching 850°C and above shall be used.
- In minor HCFs in rural areas, class 2 clinical HCW should be buried in a simple protected pit when there is no risk of contaminating underground water. All pits must be fenced to prevent authorized access.
- Yellow containers for infectious clinical waste should be located in all wards and rooms where infectious waste could be produced.
- Infectious waste containers should never be placed in public areas.

Class 3: Sharps

- Safety boxes must be located in all rooms and wards within an arm’s reach from where injections may be given.
- All class 3 sharps shall be placed in specific cardboard boxes called safety boxes, which are resistant to punctures and leakproof, designed so that items can be dropped in using one hand and so that no item can be removed.

- The safety box shall be colored yellow and marked “Danger!” or “Contaminated sharps.” Yellow is conventionally accepted color and it is advisable to stick to this color. However, in the absence of yellow colored safety box, white ones can be used.
- The safety box shall be closed when three-quarters full.
- All disposable syringes and needles shall be discarded immediately following use.
- The needle shall not be recapped or removed from the syringe; the whole combination shall be inserted in to the safety box. In field situation where there is no safety box, one-hand recapping may be acceptable. However, this does not mean that one-hand recapping is recommended.
- Under no circumstances are used syringes, needles, or safety boxes to be disposed of in normal garbage or dumped without prior treatment.
- The method of choice for destruction of full safety boxes is incineration, preferably in an appropriate double-chamber (>850°C) incinerator.
- If such an incinerator is unavailable, alternative methods of sharp disposal may be used such as needle removers and sharps pits.
- Under exceptional circumstances, full safety boxes may be incinerated in small numbers by open burning in a fenced hole.

Class 4: Pathology and Anatomical waste

- In operation theatres, all class 4 anatomical waste and placentas shall be collected separately in a plastic or galvanized metal container with a tight-fitting cover.
- They should be transported using dedicated trolleys or carts. If transportation and disposal cannot be immediately ensured, anatomical waste should be stored in the mortuary.
- When a centralized incinerator is available they shall be incinerated. When low-temperature incinerators are used, anatomical waste, or large amounts of placentas, can be difficult to incinerate and will drastically reduce the performance of the system.
- If incineration cannot be performed, class 4 anatomical waste and placentas shall be buried at a sufficient depth (> 1m) inside the HCF compound.
- Wear utility gloves when handling and transporting anatomical waste and placenta.
- Remove utility gloves after handling waste. Wash and dry them daily and when visibly soiled.
- Wash and dry hands or use an antiseptic hand rub.

Class 5: Hazardous pharmaceutical and cytotoxic waste

- Hazardous pharmaceutical waste and cytotoxic waste shall be repacked in specific bags marked “Danger! Hazardous pharmaceutical and cytotoxic waste” and they shall be sent to the medical store department that shall ensure their disposal at the central level.
- Class 5 waste shall be incinerated in a pyrolytic incinerator at a minimum of 1,200°C, or it should be encapsulated and safely buried in a deep pit depending on the depth of local water tables.

- The bottom of the pit should be 1.5m away from the ground water table.
- Class 5 hazardous pharmaceutical wastes and cytotoxic waste containing heavy metals shall not be incinerated. For disposal of pharmaceutical wastes please refer to DACA's guidelines.
- For this specific category of waste, inertization may be foreseen. In this case the residue can be disposed using landfill.
- Cytotoxic waste should never be discharged into the environment or natural water bodies like river, lakes, or landfills.

Class 6: Highly infectious waste

- Highly infectious waste from the medical diagnostic laboratory of the HCF—such as media and culture plates—shall be collected, preferably in leak-proof yellow bags suitable for autoclaving and properly sealed. It shall be autoclaved at a temperature of 121°C for at least 20 minutes at source, i.e. in the medical Diagnostic laboratory itself.
- Disinfected waste shall be collected and treated with class 2 hazardous HCW.
- If a distinct autoclave is not available at the medical diagnostic laboratory, highly infectious waste shall be disinfected in 0.5% solution of sodium hypochlorite and left overnight. It shall than be discarded in a specific yellow bag properly and sealed and discarded with class 2 hazardous HCW.
- If none of the above treatment options can be ensured, highly infectious waste should, at minimum, be packed in a specific yellow bag that shall be sealed and directly discarded with class 2 hazardous HCW—this option shall remain exceptional.
- Class 6 wastes from isolation wards or permanent treatment centres (e.g., cholera) shall always be incinerated onsite.

Class 7: Radioactive waste

- All radioactive waste of class 7 shall be stored to allow decay or decomposition to diminish their radioactive nature. Length of storage varies by radioactive waste type depending on their chemical nature and half-life.
- They shall be placed in a large container or drum and labeled with the radiation symbol showing the radio-nuclide's activity on a given date, the period of storage required, and marked "Caution! Radioactive waste."
- Containers or tanks with radioactive waste that have not decayed to background level shall be stored in a specific marked area, with concrete walls at least 25 cm thick.
- Noninfectious radioactive waste, which has decayed to background level, shall follow the class 1 non-risk HCM stream, while infectious radioactive waste which has decayed to background level shall follow the class 2 clinical HCW stream.
- Liquid radioactive waste shall be discharged into the sewage system or into a septic tank only after it has decayed to background level in adequate tanks.

Class 8: Waste with high contents of heavy metals (special hazardous waste)

- Wastes with high contents of heavy metal should normally be treated in specific recovering industries. Alternatively, as for chemical waste, it should be encapsulated for handling and disposal.
- Wastes with high contents of mercury or cadmium shall never be incinerated because of the risk of atmospheric pollution with toxic vapors.
- In case of a spill from a broken thermometer or blood pressure equipment the following procedure is recommended: put examination gloves on both hands; collect all droplets of mercury with a spoon and place it in a small, closed container for disposal or reuse; disinfect and clean the area where the equipment was broken.
- Mercury is a potent neurotoxin, especially during fetal and infant development. Please follow appropriate guidelines for mercury disposal— it enters the environment when released in to water bodies and air, and thereby contaminating lakes, rivers, and streams, and polluting the ambient air.

Class 9: Effluents

- All effluents in HCFs shall be drained to a septic tank or cesspool for both storage and treatment in the compound of the HCF.
- If it is necessary to discharge the waste through municipal sewer line, all liquid infectious waste shall be discharged only after being treated according to WHO standards.
- Waste water from HCFs should not be released into the environment without treatment because they may contain various potentially hazardous components such as microbiological pathogens, hazardous chemicals, pharmaceuticals and radioactive isotopes. The proper treatment of waste water from HCFs is very expensive and cannot be currently foreseen in every HCF of Ethiopia. However, the basic steps described above should be applied to contribute to the reduction of the public health risk associated with liquid waste and waste water.

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