

**Environmental and Social Impact Assessment (ESIA) Report
for BSL 3 National Reference Laboratory
Africa CDC Regional Investment Financing Program**

**FDRE Ministry of Health and the Ethiopian Public Health
Institute (EPHI)**



Final Draft ESIA Report

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List of Abbreviations

ACRIFP	Africa CDC Regional Investment Financing Program
AMR	Antimicrobial Resistance
APM	Air pressure monitoring
BAS	Building Automation System
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSL	Biosafety 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
FECCC	Forest Environmental and Climate Change Commission
FMOH	Federal Ministry of Health
GoE	Government of Ethiopia
GF	Global Fund
GTP	Growth and Transformation Plan
HCF	Health Care Facility
HCW	Health Care Waste
HCWM	Health Care Waste Management
HIV	Human Immunodeficiency Virus
HSDP	Health Sector Development Plan
HVAC	Heating, Ventilation, and Air Conditioning
HWMP	Health Waste Management Plan
IPPS	Infection Prevention and Patient Safety
LEMC	Laboratory Medical Equipment Maintenance Centre
MDG	Millennium Development Goals
MOH	Ministry of Health

MPA	Multiphase Programmatic Approach
OP	Operational Policy
PCZ	Primary Containment Zone
PHEM	Public Health Emergency Management Unit
PHID	Public health infrastructure directorate
PPSD	Project Procurement Strategy for Development
PTPC	Proficiency Testing Panel Production Centre,
PVC	Polyvinylchloride
RHB	Regional Health Bureau
SCZ	Secondary Containment Zone
SNNPRS	Southern Nations, Nationalities, and People's Regional State
TB	Tuberculosis
TCZ	Tertiary Containment Zone
WHO	World Health Organization

Executive Summary

Introduction

Though Ethiopia has made tangible progress to improve health care system for the provision of quality services, there are several gaps and challenges which are not addressed as well. Most of the laboratories in the health care system including the National Reference Laboratories function in facilities with sub-optimum infrastructures, poor safety working environment, shortage of equipment, supplies interruption and huge gaps in the implementation of Laboratory Quality Management System. The overall desire of the Government of Ethiopia is to have the highest possible level of health and quality of life for all its citizens, attained through providing and regulating a comprehensive package of promotive, preventive, curative and rehabilitative health services of the highest possible quality in an equitable manner. To tackle these problems, the government of Ethiopia plans to construct Biosafety Level Three (BSL3) National Reference Laboratory and associated facilities at Ethiopian Public Health Institute (EPHI). The EPHI Strategic Plan Management (2015/16 to 2019/20) and the Ethiopian Action Plan for Health Security (2018-2022) foresee the construction and equipping of the proposed BSL-3 National Reference Laboratory complex with the objective to elevate the capacity and status of the institute to conduct specialized testing, with a focus on the diagnosis of emerging and re-emerging lethal pathogens.

Conventional EIA methodological approaches were applied for carrying the assessment which includes the following: desk review of relevant documents, interview with specialists, site assessment and observations, public and stakeholder consultations, and secondary data collection for establishing the environmental & socio-economic baseline conditions.

Project Description

The Project Development Objective is to strengthen the Africa CDC's regional disease detection and response systems and link them together into an effective network of networks. It will support Africa Centre for Disease Prevention and Control (CDC), Ethiopia and the Southern Africa regional collaborating centre in Zambia to establish infectious disease control systems for the benefit of African Union member states and its citizens. In Ethiopia 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; (iv) equipping and furnishing 8 Biosecurity Level 2 (BSL-2) district laboratories already constructed by the Global Fund; and (v) a set (4) of programs designed to improve laboratory capacity building and operational effectiveness.

This ESIA report presents findings of the assessment which was conducted to identify potential environmental and social impacts associated with the proposed BSL3 national reference laboratory complex and mitigation strategies for the likely impacts. In addition, a standalone Infection Control and Waste Management Plan (ICWMP) has been prepared for the management of potential environmental and social risks associated with the BSL3 national reference laboratory complex. For the BSL2 laboratories, an Environmental and Social Management Framework has been prepared. The ESIA, ESMP and the Infection Control and Waste Management Plan (ICWMP) will be updated during

implementation (i.e. during the BSL3 lab complex design stage before civil works begin) to consider environmental and social issues associated with decommissioning old incinerators, wastewater management system and the capacity of Kotebe waste treatment plant and Sandafa Sanitary landfill for handling of incineration residues and wastewater sludge.

The BSL-3 national reference laboratory will be designed and operated in accordance with guidance for BSL-3 laboratories established by reputable international organizations (CDC 1999, NIH 2001, WHO 2004). The laboratory complex will be tested for verification that the design and operational parameters have been met prior to operation.

Legal, Policy and Administrative Framework

Ethiopia has several Acts and Regulations related to Environmental Social and Impact Assessment (ESIA) and healthcare waste management. The Ethiopian legal and policy framework applicable for this project include:

- Environmental Policy of Ethiopia
- Environmental Proclamation 299/2002, Environmental Impact Assessment
- Proclamation 513/2007, Solid Waste Management
- Proclamation 300/2002, Environmental Pollution Control
- EIA Procedural Guideline, July 2004
- The Guideline for Waste Handling and Disposal in Health Facilities (2006)

Two of the World Bank Safeguards Policies, namely OP/BP 4.01 and OP 4.11 are also applicable to this project and have been triggered. The fact that the proposed BSL 3 laboratory project activities would largely entail construction of new buildings within EPHI premises, which is already owned by the proponent, it will not seek involuntary acquisition of land and hence will not trigger OP/BP 4.12 on Involuntary Resettlement. 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. Because Ethiopia ratified different conventions, it has international obligations on proper management of hazardous wastes and minimization of dioxins emission. This has implications for the medical waste management and proper operation of incinerators. Air emission from incineration of decontaminated wastes and effluents from the proposed BSL3 national reference laboratory should fulfil the requirements of the relevant World Bank Group Environment Health and Safety Guidelines including the General Guidelines, industry specific guidelines for Healthcare Facilities and Waste Management. The project will also be in compliance with Good International Industry Practices (GIIP) such as WHO guidelines for healthcare facilities and laboratory biosafety

This project has been considered as an environmental assessment category A project. This is because: 1) the occupational and public health risk associated with highly sophisticated BSL-3 lab; 2) the risk associated with medical waste incinerators; 3) the risk associated with medical wastewater; 4) the proposed BSL-3 lab and on-site wastewater management facilities are in densely populated area in Addis Ababa; and 5) the existing waste management infrastructure and management system are inadequate.

Environment and Socio-Economic Baseline

Addis Ababa lies at an elevation of 2,200 metres and is a grassland biome, located at 9°1'48"N 38°44'24"E Coordinates: 9°1'48"N 38°44'24"E. According to 2007 population census, a total population of Addis Ababa was 2,739,551, but the city recent population annual growth rate is high with an estimated, as of 2017, about 4 million of a total 108,798.05 Ethiopian population. Addis Ababa is a Capital of Ethiopia and the seat of the African Union (AU), and a Chartered City; having three layers of Government: City Government at the top, 10 Sub City Administrations in the Middle, and 99 Kebele Administrations at the bottom. Moreover, Addis Ababa is home to 25% of the urban population in Ethiopia and is one of the fastest growing cities in Africa. The economy is growing annually by 14%. However, unemployment and poverty levels in Addis Ababa remain high, estimated at 23.5% and 22% respectively.

The proposed BSL 3 NRL project will be situated within the campus premises of the Ethiopian Public Health Institute (EPHI) which is found in Gullele Sub City, Woreda 09, on Swaziland Street. There are residential and business facilities around EPHI campus which include Commercial Bank of Ethiopia (about 1.5 km), Ethiopian Pharmaceuticals Supply Agency (about 1km), Shops (about 1km), Pharmacies (about 1km), and health care facilities (about 2km). In Addis Ababa, sewage disposal is the responsibility of the Addis Ababa Water Supply and Sewerage Authority (AAWSSA). It operates with seventeen wastewater treatment plants and the main ones are Kality and Kotebe The Kality Wastewater Treatment Plant had capacity to treat 7,600 m³ wastewater treatment per day but recently it has been upgraded with additional investment and technology so that it could treat 100,000 m³ wastewater per day. The Kotebe treatment plant (with capacity of 85,000 m³/day) receives only sludge from vacuum trucks that empty septic tanks.

Alternative analysis

Different project alternative options were considered including the “no action” alternative was considered to evaluate the scenario in the absence of the project taking place. The “No action” option was not preferred for several reasons. Firstly, 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. 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 diseases.

Various alternatives for management of hazardous medical wastes have been considered. The incinerator which are currently found in Ethiopian Public Health Institute are old and do not fulfil the emission requirements of the World Bank EHS guideline. Hence, they will be decommissioned from the site following manufacturer’s recommendations and procedures before BSL 3 NRL complex becomes operational. Hence, the following options were considered for management of solid infectious solid medical wastes. First, transportation of the decontaminated solid medical wastes from the BSL3 lab to an existing national centralized medical waste incineration facility located 90 Km away from Addis Ababa. Nevertheless, this option is risky and expensive in the context of Ethiopia. The second option is on-site treatment using pyrolysis incinerator with a capacity to burn 50 kg per hour with emission reduction device control (Fabric filter coated with catalyst) made from PTFE, with parallel dedusting, lower contamination of filter dusts because of PCDD/PCDF destruction at the catalytic surface that have high efficiency reduction of dioxin up to <0.1 ng TEQ/m³. The second option is the preferred option at this stage. However, since this project will finance the design (and feasibility study) of the BSL3 lab during project implementation, the current ESIA will be updated (together with the

relevant ESMP) before civil works are contracted (or commence). Updating of the ESIA, ESMP and ICWMP during implementation will also cover the decommission of the existing old incinerators.

Fly ash and bottom ash from incineration is generally considered to be hazardous, because of the waste would have a heavy metal content and dioxins and furans. The waste will be collected and then solidified with cement/ encapsulated in double containers made from polyethylene material to transport in safe manner to disposal site utilized by Kotebe waste treatment plant for landfilling. As plan B, Sendafa Sanitary landfill will be considered for final disposal of handling incineration residues if this would be socially and environmentally feasible. The updating of the ESIA, ESMP and ICWMP during implementation will also consider the assessment of the capacity of Kotebe waste treatment plant and Sendafa sanitary landfill for handling incineration residues.

Wastewater (Effluent) Management Alternatives: Use of a public sewer line is one of the options considered for treating and disposing liquid waste generated from the proposed BSL 3 lab at the municipal main or trunk sewer. This involves the construction of system to connect the municipal sewer line and it is inexpensive. However, this alternative is not possible currently because there is no municipal main or trunk sewer to which an EPHI sewer system could be connected. The proposed NRL project will develop its own septic tank at EPHI to dispose its own sewage. Septic tanks would be constructed according to US EPA or international standard and monitored to avoid ground water pollution. The BSL 3 laboratory will establish an appropriate liquid waste treatment and management methods. A designated waste treatment facility will be constructed in the institute. Therefore, the design of the BSL 3 lab complex will also consider the waste water treatment system. The system will be designed in such a way to reduce the level of pollution load which can primarily be defined in terms of BOD, COD, total organic carbon, oil and grease, total coliform etc. Reference would be made to standards for effluent discharge into public sewers specified in the World Bank Group EHS guideline (summarized in table 9). As it is the case for final disposal of handling incineration residues, Sendafa Sanitary landfill also will be considered for final disposal of wastewater sludge if this would be socially and environmentally feasible. Updating of the ESIA, ESMP and ICWMP will also consider the assessment of the capacity of Kotebe waste treatment plant and Sendafa sanitary landfill for wastewater sludge.

Consultation of Stakeholders and information disclosure

Consultation with relevant stakeholders (from community representatives, representatives of religious institution and with members of the different sector offices and participants from the EPH) was conducted in the following stages: i) during early data collection stage (January 22, 2019) ii) on the first draft ESIA (February 28, 2019) and iii) on the final draft ESIA (May 2, 2019). The consultation helped to identify the concerns of the stakeholders. It also enabled the stakeholders to have awareness on and feedback on mechanisms proposed for management of environmental and social risks associated with the BSL3 national reference laboratory complex. consultation was conducted at the Ethiopian Public Health Institute with participants drawn from elders, representatives of religious institution and with members of the different sector offices and participants from the EPHI. The Final ESIA has also been publicly disclosed by the client and the World Bank on 20 June 2019.

Environmental and Social Impacts and Mitigation Measures for the BSL3 NRL Complex Construction phase

The potential environmental effects anticipated to occur during construction phase are mainly concentrated with the working area. Construction phase will result on land degradation, creation of waste leftover from construction materials, local air pollution, leakages of waste waters as a result of certain processes, as well as with requirements toward safety at work, etc. For prevention of such

adverse effects a set of measures has been proposed, like fulfilment of workers safety norms foreseen in the Construction Law.

Impacts on Ecological Resources and Biodiversity: The EPHI BSL3 National reference laboratory Building will be constructed at existing EPHI compound and hence will have reduced impact on threatened or endangered species habitat or buffer areas. A small portion of vegetation and trees would be removed under foundation footings and other parts of the building's base. As mitigation, limit extent of vegetation and tree clearing and replant and re-vegetation clearing/Re-vegetating areas promptly.

Impact on Geology/Soils: Except for the temporary disturbance of up to a depth of a few feet on parts of one-quarter acre of land during site preparation and construction, there would be a very minor/negligible effect upon geology, soils, or seismicity. To minimize it, soil erosion prevention measures would be in place during the construction phase to minimize erosion from storm water;

Impact due to improper construction and demolition waste management: Demolishing and construction of the existing building and construction activities will result in generation of waste. This solid waste would probably be disposed at the Addis Ababa landfill area. Additionally, the project could generate very minor amounts of excess uncontaminated soil from excavation activities. Construction and demolition wastes should be segregated and separated for recycling of some useful waste materials and Hazardous waste will not be mixed with other solid waste generated and would be managed by way of incineration or land-filling.

Occupational health safety (OHS) Risks: All workers including new entrants will be oriented/inducted on safe work practices and ensure that they adhere to it. Regular drills would constantly follow on various possible incidences. Appropriate signage will be posted to warn staff and/or visitors that are not involved in construction activities of dangerous places. Accidents: contractor will adopt best transport safety practices with the goal of preventing traffic accidents and minimizing injuries suffered by project personnel and the public.

Electrical and Explosive Hazards: All Equipment need electric power, without provisions for electrical safety, there is a risk of electric hazard in the site. Exposed or faulty electrical devices, such as circuit breakers, panels, cables, cords and hand tools, can pose a serious risk to workers. In addition, most of the construction equipment use gasoline so that they would be gasoline containers risk of explosive. All laboratory electrical equipment would be earthed/grounded, preferably through three-prong plugs and gasoline would be placed away from fire.

Traffic accident impacts; Construction activities may result in a significant increase in number of vehicles during transport of construction materials and equipment, which will lead to increasing risk of traffic-related accidents or injuries to workers and EPHI community. The project will adhere to the application of salient practices from the WBG EHS Guidelines for Community Health and Safety in section of Traffic Safety.

Impact on Air quality: Contractors will use dust screens or nets in windows, doorways and ventilators of rooms where demolition or other dusty construction activities are occurring and ensure good housekeeping and clean construction operations. Trucks would be covered during haulage of construction materials and will be diverted away from busy areas of the institute;

Impact of noise and vibrations: Contractor will be careful when selecting equipment to avoid use of old or damaged machinery with high level of noise emissions that would have a negative impact in the environment. Contractors will cordon off construction site with noise absorbing materials; the contractor would ensure that noise levels emanating from machinery, vehicles and noisy construction activities are kept at a minimum for the safety, health and protection of people in the nearby buildings.

Decommissioning of the existing old incinerators: Potential chemical wastes to be generated from the decommissioning and demolition of the incinerators and associated ductworks include residual ash

and asbestos-containing materials. substances or chemicals (in any form, quantity and concentration), including asbestos, dioxins, polychlorinated biphenyls (PCBs) and heavy metals (HMs) would cause pollution or constitute a danger to health or risk of pollution to the environment. Decommissioning of the incinerator will be conducted under full containment to avoid the release of any residual ash to the environment, which could be generated during the decommissioning works in both phases.

Operational Phase

The proposed BSL 3 laboratory complex will be expected to generate about 20 kg of solid wastes (gloves, pipette tips, culture tubes, tissues, and other wastes) per day and an average 100 kg per week. Other non-hazardous solid waste would be estimated to be about 5 kg per day with 15 kg per week. All wastes generated in the laboratories of the facility (including sample packaging materials, culture materials, petri dishes, PPE, and associated process wastes) would leave the laboratories only after decontamination using the facility's autoclave or after being chemically sterilized. Disinfected / sterilized wastes will finally be incinerated and disposed of appropriately. Medical wastewater and sanitary liquid waste will be generated from the proposed BSL-3 facility. Sanitary waste would be generated from such activities and from toilets, showers, and sinks in the building bathroom facilities. It is estimated that the BSL3 lab complex will generate a maximum of 360 litres of medical wastewater per week and about 1640 litres of sanitary liquid waste per week. All effluents will be disinfected and drained to a septic tank or cesspool and will finally be treated at the EPHI compound before final disposal.

Impacts on Ecological Resources and Biodiversity: the operation of the proposed BSL-3 lab would have little effects on biodiversity if Infectious microorganisms handled in the proposed BSL3 lab might be introduced into the environment. To avoid these personnel working on the BSL 3 NRL complex would be trained on emergency preparedness and responses and handling of infectious materials and waste management.

Impacts on Geology/Soils: there would be no effect from the proposed BSL-3 NRL facility operation on geology, soils, or seismicity.

Impact of escaping of Infectious Agents from BSL-3 Containment: In the BSL 3 NRL complex, there would be highly infectious agents in storage, analysis or culture processing areas. So, there is a possibility of escaping infectious agents from BSL-3 containment due to hardware failure (HEPA filter), miss use or theft and during sample and waste handling, transportation, and storage. And could cause potential risks resulting in life-threatening for personnel working in the BSL 3 laboratory and community. As a mitigation strategy, EPHI will ensure the implementing of laboratory access control, regular maintenance of HEPA filter, regular inventory system and training to the employees.

Impact of escaping of Infectious Agents from BSL 2 labs, PTPC and biobank centres: In the PTPC and biobank would be infectious agents in storage, PT diagnosis process or culture. So, that there would be a possibility to escape infectious agents from PTPC and biobank. It could cause potential risks resulting in life-threatening for personnel working in the centre and community. The mitigation measures would be implementing of access control, regular maintenance of HEPA filter, regular inventory activities and training to the employees.

Occupational Health and safety impacts associated with BSL 3 NRL complex operation: Primary hazards to personnel working in Biosafety Level 3 is related with highly infectious agents. Moreover, there are hazards from BSL 2 labs, PTPC and biobank operation. 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 such as centrifugation, mixing, pouring and spilling of culture fluids. Inoculation hazards may come due to needle sticks and lacerations. Ingestion hazards might be a result of splashes to the mouth, eating food in laboratory, and mouth pipetting, and contamination of skin and mucous membranes can occur via

splashes or contact with contaminated fomites. In addition, if the BSL 3 laboratory does not have appropriate work processes, engineering, and administrative controls, the wastes from the laboratory facilities and practices can have serious impact on the community. Moreover, there is also a risk of accidental leakage or spillage from specimens due to poor specimen handling.

As mitigation measures, a containment, good laboratory practices and administrative controls at BSL-3 laboratory facility can reduce the risks, and more emphasis would be given on primary and secondary barriers to protect personnel, community, and the environment from exposure to potentially infectious aerosols. It is therefore essential to maintain high standards of safety in BSL 3 laboratory and recommended safety for BSL 2 labs, PTPC and biobank. Laboratory personnel working in BSL 3 lab, BSL 2 labs, PTPC and biobank must receive specific training in handling pathogenic and potentially lethal agents and would be supervised by senior and competent staff in handling infectious agents and associated procedures. All procedures involving the manipulation of infectious materials would be conducted within BSCs or other physical containment devices and a BSL-3 laboratory must have special engineering and design features. Moreover, the BSL 3 laboratory doors must be self-closing and must be separated from areas that are open to unrestricted traffic flow within the building. To avoid accidental leakage or spillage from specimens, secondary containers, such as boxes, will be used, fitted with racks so that the specimen containers remain upright.

Risk from handling of infectious materials and specimens in the proposed BSL-3 NRL complex:

The BSL 3 laboratory, BSL 2 labs, PTPC and biobank are expected to deal with infectious agents during specimen handling. So, there would be a risk of exposure to infectious agents during performing procedures and waste handling. As a mitigation strategy, EPHI would ensure that employees strictly comply with standard operating procedures; properly use and maintain their PPE and obtain the necessary training. Specimen containers would be robust and would not leak when the cap or stopper is correctly applied. No material would remain on the outside of the container. Containers would be correctly labelled to facilitate identification and Standard precautions would always be followed.

Impact of improper use of equipment in the BSL 3 NRL complex: Laboratory workers are at risk for repetitive use of laboratory equipment such as pipetting, centrifuge, BSC homogenizers, shakers, blenders, sonicators, freezers, autoclave and other equipment. Certain items of equipment may create hazards when they are used, and the common hazards related to laboratory equipment are Aerosols, splashing and tube breakage rotors and impaired ultrasonic hearing, dermatitis, burning, splash and spillage. In addition, due to improper use equipment-related accidents might occur. The mitigation measures would be training of workers in equipment operating and handling techniques during operation, and operation of equipment, periodic maintenance and calibration would be according to the manufacturer's instructions.

Impact of contamination of the BSL 3 NRL complex Facilities: The BSL 3 laboratory performs analysis on the human specimen. So, during the handling and processing of the samples; space, furniture, and equipment could be contaminated by hazards materials such as infectious agents and chemicals. As a mitigation to maintain safe and sterile work surfaces; a standard operating procedure for properly maintaining, cleaning and disinfecting equipment, work and non-work surfaces would be implemented. In addition, the WHO Laboratory Biosafety Manual 3rd edition, and CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) will also be implemented.

Potential impact during the operation of Central Warehouse; a large quantities of hazardous chemicals would be stored in the central warehouse. A leaked chemical, especially when it is volatile or a gas at room temperature can cause intoxication and contact with liquefied gases causes severe frostbites in addition Stored chemicals can also cause accidental fire or explosions resulting health damage, Fire and explosions. As a mitigation, EPHI will implement 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

Impact of fire outbreak: All staff shall have training in fire control through regular firefighting drills. Fire extinguishers will be available in accessible area near to fire risk area and ensure that all fire-fighting equipment is regularly maintained and serviced. Fire hazard signs such as 'No Smoking' signs will be provided. Directions to exit in case of any fire incidence and emergency contact numbers shall be provided. The contact/emergency numbers shall be displayed within the laboratory

Chemical hazard in the BSL 3 NRL complex building: Occupational chemical exposure may result from laboratory procedures performing and handling of chemicals. All staff would have training in controlling of chemical hazardous and handling. Only amounts of chemicals necessary for daily use will be stored in the laboratory. Implementation of engineering and administrative control measures to avoid the release of hazardous substances into the work environment. Appropriately equipped first-aid stations will be easily accessible throughout the place of work, with Materials Safety Data Sheets (MSDS).

Electrical and explosive hazards in the BSL 3 NRL complex building: In BSL 3 NRL complex there are several types of Equipment needed electrical power. Without provisions for electrical safety, there is a risk of electric for BSL 33 NRL complex. It is essential that all electrical installations and equipment are inspected and tested regularly, including grounding systems. Circuit-breakers and earth-fault-interrupters will be installed in appropriate laboratory electrical circuits. All equipment will be disconnected the attached to high-voltage or high-amperage power sources from the source or provide a lockout device on the breaker. Staff will train of electrical safety.

Ergonomic hazards in the BSL 3 NRL complex building: Laboratory workers are at risk for repetitive motion injuries during routine laboratory procedures such as pipetting, working at microscopes, operating machine and working on BSC workstations. By becoming familiar with how to control laboratory ergonomics-related risk factors, employers can reduce chances for occupational injuries. Selecting tools and designing work stations that reduce force requirements and holding times, and which promote improved postures, implementing administrative controls into work processes, such as job rotations and rest or stretch breaks.

Impact of air pollution due to waste incineration: Medical waste incinerations emit toxic air pollutants and toxic ash residues that are the major source of dioxins in the environment. To avoid dioxin production, no chlorinated plastic bags (and preferably no other chlorinated compounds) would be introduced into the incinerator. Red bags must not be incinerated as red colour contains heavy metals, which causes toxic emissions. As a mitigation strategy, careful waste segregation and Wastes with polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs would never be incinerated, training programs, as well as attention to materials purchased, will be considered in minimizing the environmental and health impacts. In addition, EPHI would purchase an incinerator that meets WB emission standards (best available technology) and adhere to the best environmental practices recommended by Stockholm convention.

Misuse and/or theft of infectious agent, laboratory equipment/supplies in the BSL 3 NRL complex building: Such a deliberate and/or unexpected misuses and thefts can potentially end up in the release of microorganisms and biological materials that may affect the environment and community health. In addition, in laboratory there are very expensive types of equipment that can be misused and/or stolen. Establish system for physical security, personnel security, material control & accountability, and information security. These measures will be developed to protect against the insider threat, or outsider threat and any natural or manmade events that could cause a release.

Risk associated with collection/handling and storage of waste at BSL 3 NRL complex building: During the operational phase of the BSL 3 laboratory it is anticipated that solid and liquid wastes are generated daily. Most of the wastes generated would be considered as highly infectious. The improper

handling, treatment and disposal waste can cause serious health problem for workers, community and environment. As a mitigation measures, BSL 3 NRL complex would adhere to the application of WHO Laboratory Biosafety Manual 3rd edition and WBG EHS Guidelines which represent best practices and experiences in hazardous waste management.

Risks associated with waste transportation within EPHI campus and offsite: Medical waste may contain potential pathological organisms which if improperly managed may be a risk to healthcare staffs and public during transportation of waste. To avoid this, all waste bags would in-place and transportation using carts, trolley, or containers assigned for this purpose only and transport workers would use PPE during handling waste. Moreover, training on waste management would be provided to all waste transport workers. All waste containers designated for off-site shipment would be secured and labelled with the contents and associated hazards and be properly loaded on the transport vehicles before leaving the site, and waste would be placed in rigid, leak-proof containers before being loaded and covered with lids.

Risk associated with final waste disposal: The disposal and storage of these wastes without treatment leads to contamination of surface and groundwater through long term leachate accumulation from the disposal sites and ultimately disturbs the ecological and environmental balance. Personnel working on waste disposable would trained on waste management and they would wear necessarily during waste disposable. Bottom ash would be managed separately from fly ash and other flue gas treatment residues to avoid contamination of the bottom ash for its potential recovery. Fly ash and bottom ash will be collected and then solidified with cement/ encapsulated in double containers made from polyethylene material to transport in safe manner to disposal site utilized by Kotebe waste treatment plants for landfilling. Alternatively, the homogeneous mixture would be transported in liquid state to a Kality wastewater treatment plant and then the treated sludge will be disposed in secured manner at landfilling disposal site utilized by Addis Ababa water and sewerage Authority. As plan B, Sendafa Sanitary landfill will be considered for final disposal of handling incineration residues if this would be socially and environmentally feasible.

Impacts of Improper waste water treatment at EPHI BSL 3 NRL Complex: Several risk factors can reduce the efficiency of the septic tank. The risk can be imparted during designing or operation phase, resulting risk for worker, and community health and environment pollution. EPHI would be transported to AAWSSA Kotebe treatment plants to treat and dispose sludge, using vacuum trucks with empty septic tanks. The waste also needs to meet the standard summarized below table to be discharged into publicly operated sewage collection and treatment systems at Addis Ababa. As it is the case for final disposal of handling incineration residues, Sendafa Sanitary landfill also will be considered for final disposal of wastewater sludge if this would be socially and environmentally feasible.

Analysis of Abnormal Events and Accidents for Facility Operation: The potentially hazardous material to be handled in the proposed BSL 3 facility would consist of highly infectious microorganisms in containers holding liquid suspensions or on semi-solid media. Accident scenarios usually catastrophic events such as earthquake, fire, explosions and airplane crashes, normally considered as initiating events are having the potential to increase risk on highly infectious releases. The accident scenario would be dangerous for workers, the community and environment, causing a serious health problem. BSL 3 NRL would have an emergency preparedness and response plan. In an emergency response mode, the responder would enter only after ascertaining the risk and donning appropriate personal protective equipment.

Emergency Preparedness and Response: An emergency is an unexpected event when the BSL 3 laboratory operation loses control, or could lose control, of a situation that may result in risks to human health, property, or the environment, either within the facility or in the local community. Therefore, the BSL 3 facility emergency preparedness and response plan would be commensurate with the risks of the facility, and an Emergency Preparedness and Response Plan, incorporated into and consistent with, the facility's overall ES/OHS.

Environmental and Social Management Plan (ESMP)

An Environmental and Social Management Plan (ESMP) has been proposed for construction works and operation of laboratory facility. The ESMP identifies potential environmental and social aspects that should be mitigated, parties responsible for implementing and monitoring actions, associated costs, indicators and training or capacity building needs and reporting. Institutional responsibility of implementing this ESMP will be the Project Coordination Team, under Public Health Infrastructure Directorate (PHID) at FMOH. A key role and responsibility of the team would be to review consultants' reports for compliance with the ESMP, monitoring implementation of mitigation actions by contractors, coordinating training and capacity building where planned, periodically report to FMOH about implementation and progress of the ESMP. Monitoring will verify if predicted impacts have occurred and check that mitigation actions recommended in the ESIA are implemented and their effectiveness. Monitoring will also identify any unforeseen impacts that might arise from project implementation. Monitoring will be undertaken by FMOH PHID directorate and Addis Ababa Environmental Protection Authority (EFCCC) at local administrative.

Various measures have been proposed to improve the client's capacity to manage the risks associated with the project. To maintain regulatory compliance and to protect personnel, the community and the environment from biohazards, EPHI will be responsible for appointing laboratory director, biosafety and biosecurity officer and other technical and support staff required for the BSL-3 lab complex; ensuring appropriate training is provided to personnel conducting research with biohazards; ensuring that research conforms to the provisions of best international practices. The BSL-3 facility will also recruit and deploy HVAC technician, electrical technician, equipment and instrument maintenance technician, security staff, incinerator operator, cleaners, wastewater treatment plant operator. These staff will help to ensure proper implementation of the ESMP and ICWMP; and their roles and responsibilities are described in section 2 of the ESIA.

Procedures, roles and responsibilities for addressing grievances and resolving disputes are also presented under this chapter. Every aggrieved person shall be able to trigger this mechanism to quickly resolve their complaints. In general, the proposed project has potential to significantly improve quality of laboratory, and efficiency of service provision in the national as well as at regional with socio-environmental benefits such as improved medical surveillance and emergency public health management services, resulting reduced morbidity, improved quality of life for the population, and increased productivity of labour. Possible socio-environmental impacts can be adequately controlled with mitigation measures presented in this report.

Capacity building training for ESMP implementation monitoring will be provided to relevant staff of FMOH PHID, EPHI, AAEFCC and BoLSA to enhance their skills in environmental monitoring during the operational phases of the NRL BSL-3 laboratory. The budget allocated to support the capacity building will be 79, 500 USD. The overall indicative ESMP and environmental monitoring implementation budget will be **1,337, 275.00 USD**.

1. Introduction

Ethiopia has an estimated 2017 population of 105 million, and is the most populous landlocked country in the continent of Africa and the second-most populous country of Africa after Nigeria. In the past two decades, the Government of Ethiopia has invested heavily in health system strengthening guided by its pro-poor policies and strategies resulting in significant gains in improving the health status of Ethiopians. As a result, Ethiopia has done remarkably well in meeting most of the MDG targets. Mortality and morbidity due to HIV/AIDS, Tuberculosis and malaria has reduced markedly. Death due to malaria has declined with a significant decrease in admissions and deaths of under-five children by 81% and 73% respectively. HIV new infection has dropped by 90% and mortality cut by more than 50% among adults. Besides, Ethiopia is one of the few sub-Saharan African countries with “rapid decline” of mother-to-child transmission of HIV, with a reduction by 50% of new HIV infections among children between 2009 and 2012. Similarly, the country has achieved the targets set for tuberculosis prevention and control. Mortality and prevalence due to Tuberculosis has declined by more than 50% and incidence rate is falling significantly.

The significant gains made are as a result of the political commitment and strong leadership at all levels of government, community engagement and ownership of health programs, and the unprecedented support from development partners. Over the last 20 years, the country has successfully implemented its strategy of expanding and rehabilitating primary health care facilities. To this effect, 16,440 health posts, 3,547 health centres and about 300 hospitals have been constructed. In parallel to the construction of health facilities, investment in human resource development and management has been scaled up; reformed supply chain and logistics management to ensure continuous availability of health commodities at an affordable price in a sustainable manner; and strengthen coordination and partnership.

Although tangible progress has been made in improving health care for the provision of quality services in Ethiopia, many gaps and challenges are yet to be addressed through further efforts over the years to come. Almost all laboratories in the system across all tiers including the National Reference Laboratories at EPHI function in facilities with sub-optimum infrastructures devoid of appropriate provisions for safe working environment, the supply chain system is inefficient,

inconsistent and unpredictable, instrumentation with state-of-the-art technologies is in its infancy compounded with inefficient system for service and maintenance, weak or absent Information and Communication Technology (ICT) infrastructure to enhance network communications and to ensure seamless flow of information within the network, 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, public health researches and public health emergency management operations.

Building on the lessons learned in implementing the earlier plans and to be highly responsive to the current socioeconomic landscape, the Government of Ethiopia has developed Health Sector Transformation Plan (HSTP), which is part of the second Growth and Transformation Plan (GTP II). HSTP is also the first phase of the 20-year health sector strategy called 'Envisioning Ethiopia's Path to Universal Health Care through strengthening of Primary Health Care'. The overall desire of The Government of Ethiopia is to have the highest possible level of health and quality of life for all its citizens, attained through providing and regulating a comprehensive package of promotive, preventive, curative and rehabilitative health services of the highest possible quality in an equitable manner.

This goal will be attained by the government's effort enhanced with community empowerment with sustainable finance. However, Ethiopian has a limited government financing. To tackle these problems, there needs to be an effort to offer financial protection and expansion and improving of availability of service in a bid to make basic and quality assured health care accessible to Ethiopian population. The present World Bank financed Africa CDC Regional Investment Financing Program (ACRIFP) aims at achieving this. All the afore-mentioned factors and challenges are embedded in the design of the ACRIFP. The project is to support the Government's program through the development of systems and strengthening and improve quality assured and health care services for beneficiaries.

In its broader perspective, the ACRIFP project is designed as Multiphase Programmatic Approach (MPA) and it will be implemented in Africa CDC, Ethiopia and Zambia. The project is designed

to support US\$20 million for Africa Centres for Disease Control and Prevention, US\$150 million for Federal Republic of Ethiopia and US\$60 million Republic of Zambia.

This Environmental and Social Impact Assessment (ESIA) report prepared for the construction and equipping of BSL-3 level state-of-the-art National Reference Laboratory complex to be developed in the Ethiopian Public Health Institute (EPHI). The ESIA is conducted to identify and assess the likely environmental and social impacts of the proposed BSL-3 National Reference Laboratory project, to determine their magnitude and significance, and to define management or mitigation measures designed to avoid and minimise where possible, or if not, to offset or compensate for adverse impacts and risks. In the assessment of resources needed for the implementation of the ESIA during for construction and operational stage impacts and risks, waste streams and waste management facilities, the whole BSL3 lab complex has been considered.

1.1 Background of the project

Ethiopia has a three-tiered national reference laboratory system with the existing national reference laboratory serving as the hub. At present, there are 35 laboratories, nationwide, but their facilities are, generally, inadequate for the scope of services proposed by the project and quality varies significantly among them. The EPHI Strategic Plan Management (2015/16 to 2019/20) and the Ethiopian Action Plan for Health Security (2018-2022) foresee the construction and equipping of the proposed BSL-3 level state-of-the-art National Reference Laboratory complex with the objective to elevate the capacity and status of the institute to conduct specialized testing, with a particular focus on the diagnosis of emerging and re-emerging risk group 3 ethological agents/pathogens. The construction and equipping of the proposed BSL 3 laboratory will bolster the capacity of EPHI for advanced public health researches, provision of quality referral diagnostic services and timely detection of causative agents of epidemic disease outbreaks thus facilitating quick and effective response to public health threats.

With the level of laboratory capacity to be developed by the proposed project, EPHI will be well set to effectively support the implementation of Africa CDC's strategies and initiatives for the promotion of public health in the Horn of Africa Region. The institute will be well positioned to assume continental responsibilities and functions for the advancement of public health as host for the Africa CDC and member of the Regional and Continental Networks of African National Public

Health Institutes. A new construction design for the proposed BSL-3 NRL complex will be prepared by an experienced and competent company. The Government of the Republic of Ethiopia, with funding from World Bank plans to construct a BSL-3 NRL complex. For the construction and operational activity of the BSL-3 laboratory an ESIA (which also include the ESMP) and infection control and waste management plan have been prepared.

This ESIA is therefore prepared for the proposed new BSL-3 National Reference Laboratory complex project to be developed in the premises of EPHI by incorporating site specific assessments for the future activities of the project. The report will present the overall situation in the project area, indicate possible impacts of the construction and operation phase and suggest ways of mitigating unwanted impacts to help implement the project in the most environmentally friendly manner.

1.1.1 Structure of 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, and Zonal and Woreda administration, private for-profit providers, NGOs, community-based and faith-based organizations, religious and traditional care givers (WHO 2002). Ethiopia has a devolved federal structure of governance, and the Constitution provides for shared responsibility for health policy, regulation, and service delivery between Federal Ministry of Health (FMOH), regional health bureaus, and woreda health offices. In line with Government's decentralization policy, decision making power in the sector has been devolved from FMOH to regional health bureaus and woreda health offices. Accordingly, FMOH and regional health bureaus focus on policy formulation and provision of technical support. And, woreda health offices retain primary responsibility for managing health system operations in their jurisdictions. Accordingly, currently there are 290 hospitals, 3962 health centres, and 16547 health posts under the regional and federal government which provides health care services.

The reform and restructuring program of the health sector, known as *business process re-engineering*, has led to establishment of a three-tier health care delivery system in Ethiopia (Figure 1) to deliver essential health services and ensure referral linkages. Rapidly expanding private

service providers (including for-profit and not-for-profit) are augmenting the public sector service delivery outlets, especially in the urban areas.

The first tier comprises the woreda health system that consists of satellite health posts, health canters, and a primary hospital, which together form a primary health care unit. Staffed with two health extension workers, each health post serves 3,000 to 5,000 persons. The health extension workers are expected to spend less than 20 percent of their time in their respective health posts. More than 80 percent of their time is meant to be spent on community outreach program visits to households, with a primary focus on mothers and children. The health extension workers conduct 96 hours of training for households in their catchment area on selected health extension programs. The health extension workers also follow-up on progress that households make in practicing the knowledge and skills acquired through training before they graduate as model families. In addition, the health extension workers provide selected health care services, including family planning, epidemiology, clean delivery and essential new-born care services, diagnosis and treatment of malaria and pneumonia, and management of diarrhea and dehydration using oral rehydration solution.

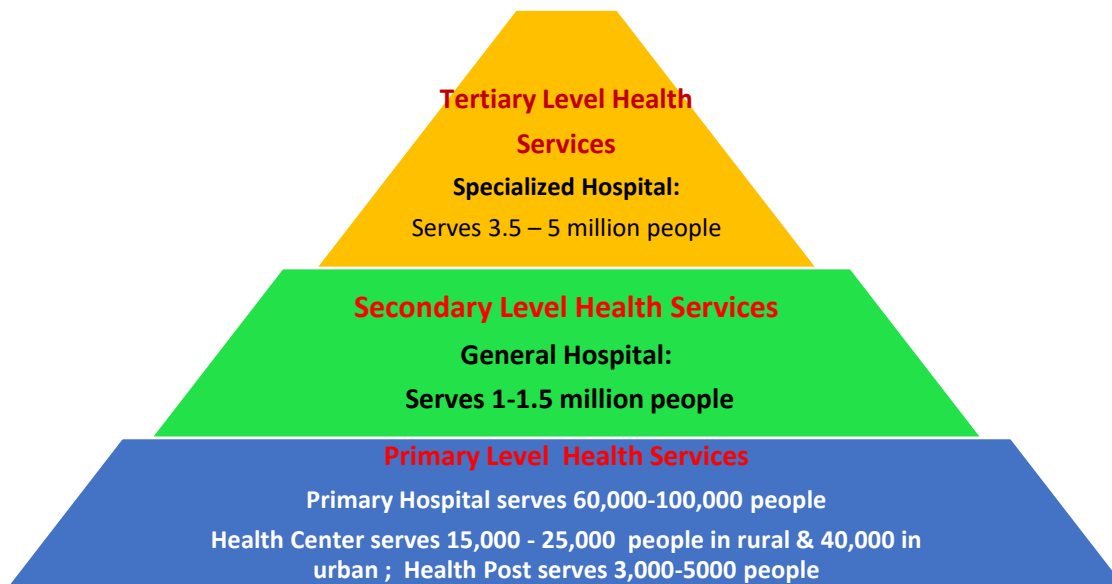
On average, a health Centre has 20 staff and provides preventive and curative services. Health Centres serve as a referral Centre and practical training site for health extension workers. A health Centre in rural areas serves a population of up to 25,000; in urban areas the population covered by one health Centre may reach up to 40,000.

Primary: Facilities at this level form the entry point of the community into the healthcare system. They include health Centres and clinics, dispensaries, and health posts, providing general preventive, curative and pre-referral care. Primary facilities are typically staffed by nurses, community health officers (CHOs), community health extension workers (CHEWs), junior CHEWs, and environmental health officers.

- A primary hospital is staffed with 53 health personnel and provides inpatient and ambulatory services to a population of 60,000 to 100,000. A primary hospital provides all the services of a health Centre as well as emergency surgical services, including Caesarean section, and access to blood transfusion services. It also acts as a referral point for health centres' in its catchment

area, in addition to being a practical training centre for nurses and other paramedical health professionals.

Figure 1: Ethiopia's Three Tier Public Health System



Secondary: Secondary care facilities include general hospitals, providing general medical and laboratory services, as well as specialized health services, such as surgery, pediatrics, obstetrics and gynecology. General hospitals are typically staffed by specialist doctors, medical officers, nurses, midwives, medical laboratory scientists, pharmacists, community health officers etc. Secondary level facilities serve as referral points for primary healthcare facilities. Each LGA is expected to have at least one secondary healthcare facility.

The second tier in the Ethiopian healthcare system is comprised of a general hospital with population coverage of 1 million to 1.5 million. This type of hospital provides in-patient and ambulatory services. With a staff of 234 professionals, a general hospital serves as a referral Centre for primary hospitals and a training centre for health officers, nurses, emergency surgeons, and other health workers.

Tertiary: Tertiary level facilities form the highest level of healthcare in the country and include Specialist Hospitals, Teaching Hospitals and Federal Referral Hospitals. They provide specialist care for patients referred from the secondary level as well as from the primary level. Other functions include teaching and research. The third tier of the system consists of a specialized hospital with population coverage of 3.5 million to 5 million and a professional staff of 440.

Almost all the fifteen BSL-2 level Reference Laboratories to be constructed by the World Bank financed ACRIFP project are going to be implemented within the health facilities found in the second and tertiary levels of the health system. The BSL-2 level Reference Laboratories are also distributed throughout the eight regional states of the country including Addis Ababa city as shown in figure 1. The proposed BSL-3 Laboratory project which is the main point of focus for this ESIA report is going to be built in Addis Ababa, Ethiopia.

The overall aim of the proposed project is to strengthen Ethiopian health 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, Strengthening of the Ethiopian Public Health Institute will allow the government to improve 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", Building resilient Public Health and Emergency Management systems, Infrastructure and project management and Human resource development detail information about the project is described in Chapter 2.

1.2 Objective of the ESIA

The general objective of this ESIA report is to assess and evaluate the existing and the anticipated impacts during construction and operation of the proposed NRL project in the selected site, propose enhancement mechanisms for the positive impacts and mitigation measures to reduce the effects of the negative impacts for the proposed project on construction. In doing so, the ESIA report will give a clear picture of the projects to the competent agency for informed decision-making processes. The specific objectives are:

- To identify potential positive impacts and their enhancement mechanisms
- To identify potential social and environmental negative impacts and to propose their equivalent mitigation measures
- To ensure that the health and environmental impacts of the proposed activities are adequately addressed prior to decisions making
- To propose possible alternative for the betterment of the environment and the society

- To inform the community about the proposed project and incorporate their view to the project design and implementation

1.3 Scope of the ESIA study

The spatial and temporal scope of the ESIA study is bounded by the location, construction and operation activities envisaged by the proposed BSL 3 NRL project. The spatial scope of the project will consist of the areas of direct and indirect impact zones. The direct impact zone is considered to be those areas where the existing biophysical, socio-economic and environmental components are likely to be directly affected by the activities of the project components. These include the EPHI campus and surrounding neighbourhoods. The project sites form the centre of influence for the direct impact zone. Accordingly, the spatial scope is centred at EPHI campus areas.

The temporal scope of the ESIA study would mainly focus on assessing the potential impacts that are likely to occur during construction and operational periods of the project. The environmental and social assessment framework would identify the direct and indirect impacts on humans, water, air, landscape, material assets and cultural heritage stemming from the implementation activities of the project. It will also develop relevant mitigation/enhancement /offsetting measures and monitoring, institutional strengthening measures to be undertaken during project implementation and operation.

The EPHI campus is in a densely built-up area. The assessment and consultations have considered the likely impacts of air emissions from incinerators in the EPHI campus on the surrounding neighbourhoods. Furthermore, management approach and disposal of residuals of the incinerators, including hazardous fly ash, have been given due attention in this assessment. Similarly, effluent management and disposal has been given due attention in this assessment.

1.4 Methodology

The methodology adopted for conducting the Environmental and social impact assessment study includes the conventional methods, which are briefly discussed below.

- **Field Surveys:** The method of field surveying is second to none in understanding the likely impacts of a given development project on the environment around the project site. The team has been mobilized for field survey to the project site in the EPHI campus. Site visit was carried out in the area for construction of BSL 3 Laboratory. The aim of the site visit

was to assess baseline conditions and how environmental and social management issues are managed by ACRIFP. Consultations with EPHI officials provided additional data to inform the ESIA on institutional capacity for applying the ESMP at EPHI levels. The team conducted observations in and around the project site at EPHI and its external surrounding area to gather essential field data. During site observation information on physical, biological and socio-economic environment has been collected. In addition, base line data collection was also done through site investigations.

- **Interviews with specialists:** Project alternatives, designs and processes were discussed with the project engineers with particular emphasis on the reasons establishing the form and scope of the proposed project. Proposed layout of the NRL laboratory, EPSI Campus Master Plan and engineering design criteria documents produced by Black & Veatch Special Project Corp responsible for the detail designing of the NRL project were consulted to define the main components of the project in developing the project description chapter.
- **Literature review:** Information on existing environmental conditions was obtained from review of various published and unpublished sources. In addition, review of the relevant healthcare waste management literature, World Bank Safeguard Policies, ESMF, RPF and various guidelines including the IFC EHS guidelines were also made. The review also examined technical and supervision documents from previous and ongoing World Bank project and programs in the health sector, namely the Protection of Basis Services Program and Nutrition Project.
- **Competent authority guidelines:** The Federal and regional legislative and institutional framework, policies, procedures and guidelines for environmental management has been reviewed. In addition, the review examined the set of national policy and legal requirements related to environment and social management in the health sector. Sociological and environmental data was also gathered by consulting and discussing with the experts in concerned stakeholder government agencies.
- **Sampling and Monitoring:** Baseline air quality was measured using a digital MultiRAE pro. RAETM air monitor device (Fig 8). The ambient air quality measurements were made on selected places found in and around the EPHI campus area with consideration for presence of potential receptors. The resulting data from the analysis will be used to establish bench mark situations as part of the assessment.

- **Stakeholder consultation with relevant Federal and Regional authorities:** Information regarding to the project was provided to stakeholders to enable them to understand project risks, impacts and opportunities. The stakeholder consultation aim was to create understanding of the project, understand local expectations of the project, and identify potential environmental and socio-economic impacts as well as to gather consensus on mitigation options. Interviews and consultation discussions were held with various GoE ministries and authorities, including those at the national and EPHI levels as well as technical experts involved with environmental and social impact assessment and management in the health sector. Specifically, formal interviews were conducted with relevant personnel in the EPHI and FMOH, experts in the Ministry of Urban Development and Construction; and experts in the Addis Ababa Bureau of Labour and Social Affairs. In addition, interviews were held with EPHI staff to assess strengths and gaps in effectively managing environmental and social effects in the sector at the regional and local level. The minutes of meeting outlining the issues raised and discussed are attached in Annex 1.
- **Community consultation:** Community participation and consultation is an important step in the ESIA methodological process. Public consultation is instrumental in assessing the socio-economic impacts of the project. Community consultation meetings have been convened to draw together the issues and concerns of the resident communities found in the neighbourhood of the EPHI campus. Participants of the community consultation included community members, women, youth and other residents in the area.



Figure 2: Showing the community consultation meeting

ESIA methodological flow: This section describes the broad principles and methodological steps of the ESIA indicating the techniques applied for impact identification, quantification, analysis and mitigation. The Environmental and Social Impact Assessment (ESIA) process incorporates several Key steps. The assessment process constitutes a systematic approach to the evaluation of a project in the context of the natural, regulatory and socio-economic environments of the area in which the project is proposed to be implemented. The process adopted to undertake the ESIA study for the NRL project is summarized below.

Step 1-Screening: Environmental and Social screening of sub-projects is carried at the initial stages of the ESIA process to determine the level of assessment that need to be carried on the sub-project. Though the type of projects falling into the different categories are essentially similar, the national environmental screening system follows a different approach from the World Bank by adopting a list of scheduled projects grouped in different categories. The environmental and social screening systems as it applies for the NRL BSL 3 project is described as follows.

1.4.1 Classification according to Ethiopian EIA Procedural Guideline

The Environmental Impact Assessment Proclamation (No 299/2002) aims primarily at making the EIA mandatory for categories of projects specified under a directive issued by the former Ministry of Environment, Forest and Climate Change (now Commission). The EIA procedural guideline published by the MoEFFC in 2003 have outlined the categories of development projects and activities that will require full, partial and no environmental impact assessment (EIA). Under schedule II activities of the EIA guideline the type of Activities that are required to conduct Preliminary Environmental Impact Assessment study report are listed. One of the activities identified under it is “*Hospitals and Dispensaries*”. As such the proposed NRL project is not directly included in the list of scheduled activities; however, apparently it is an important part of health facilities such as hospitals. Thus, it is prudent to consider the proposed NRL development project as schedule II activities listed under the section. As a result, to fulfil its requirements under the national EIA law, the project proponent (EPHI) will have to conduct and submit a preliminary environmental impact assessment study for the development project. This ESIA report is prepared towards fulfilling the national EIA requirement and will be submitted to the competent authority which in this case is the Addis Ababa EPA for review and approval.

1.4.2 Project Classification according to World Bank

The World Bank classifies a proposed project into one of four categories, depending on the type, location, sensitivity, and scale of the project and the nature and magnitude of its potential environmental impacts.

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. The project impacts may affect an area broader than the sites or facilities subject to physical works. Environmental assessment for a Category A project examines the project's potential negative and positive environmental 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.

Category B: A proposed project is classified as Category B if its 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 environmental assessment 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 may result in adverse environmental impacts.

The BSL-3 NRL Project Classification: The proposed NRL project construction, equipping and operation will be restricted within the EPHI institute premises with the exception of waste management/ pollutants generated that may go beyond the boundaries of the institute. The project will not directly affect ecosystems such as wetlands, forests, grasslands, etc. Therefore, according to World

Bank classification, the proposed NRL project is classified under *Category A*. because: 1) the occupational and public health risk associated with highly sophisticated BSL-3 lab; 2) the risk associated with medical waste incinerators; and 3) the risk associated with medical wastewater treatment.

Step 2- Scoping: The first step in the ESIA was to define the proposed project activities and the natural, regulatory (i.e. legal) and socio-economic environments in which these activities will occur. This is achieved through scoping. Scoping identifies which of the activities has a potential to interact with the environment. Scoping was conducted early in the ESIA process so that a focus on the priority issues (i.e. those that have the greatest potential to affect the natural and/or socio-economic environment) can be established for the rest of the ESIA process.

Step 3-Detailed data gathering and review: Following step 2, engineering, environmental and socio-economic data was assessed in greater detail to ensure all of the proposed project activities and their consequences were considered in all stages of the development.

Step 4 Existing environmental conditions: To identify any potential impact on and potential change to the natural and socio- economic environments, it was essential to have a thorough understanding of the existing environment prior to commencement of the proposed activities. In this regard there was a need to characterize the existing baseline environmental and socio-economic conditions including establishing the prevailing conditions for a range of media as follows:

- Natural environment media such as water, air, soil and groundwater, flora and fauna;
- Socio-economic media such as demographics, economic activity and service provisions

Step 5 Project alternatives: The initial step in defining the project was to identify, at a conceptual level, viable alternatives to the project so that a viable base-case design may be realized. Consideration of project alternatives occurred at two levels as follows:

- At the initial stage where we considered the “no development” option
- At the design stage where we explored engineering alternatives within the selected project design definition.

Once project alternatives were defined in the Project Concept stages, they are assessed and compared on financial, logistical, technical design, safety and environmental/socio-economic

criteria. The project alternative that is determined to likely result in the best balance against these criteria was typically the one that moves forward into the detailed design phase.

Step 6 Consultations: Project stakeholder consultation is a vital component of the ESIA process. The consultation process focuses on providing information on the proposed NRL development project in a manner that can be understood and interpreted by the relevant audience, seeking comment on key issues and concerns, identifying potential impacts and offering the opportunity for alternatives or objections to be raised by the potentially affected parties and other stakeholders. All relevant stakeholders were identified and consultations at all levels of the ESIA study were conducted. By conducting the consultations, the people that will be affected by or have an interest in the proposed project were having an opportunity to express their opinions and concerns.

Step 7-Identification and analysis of the environmental impacts: Key potentially beneficial as well as adverse impacts on the physical, biological and socio-economic environment associated with the construction and operation phases of the proposed BSL-3 NRL project were identified with the help of checklists, site survey and consultations with stakeholders and affected parties. In addition environmental impact analyses were carried out in three stages:

Identification- This includes description of the existing environment, determination of the project components and definition of the environment that will be modified by the project.

Prediction- Forecasting of the quality and/or spatial dimensions of the changes and estimation of the probability that the impact will occur.

Evaluation- Determination of the incidence or magnitude and significance of the impact before mitigation.

A combination of these parameters were summarized in an all-encompassing measures of significance which were the basis for identifying and prioritizing major impacts and recommending mitigating measures. The predicted environmental and social impacts are characterized as follows:

Nature of Impact:	Direct, indirect or cumulative;
Type of impact:	Positive, negative or both
Duration of impact:	Short term, medium term or long term;
Spatial scale of impact:	Localized, or widespread
Extent of baseline change:	Low, medium or high

Each impact is evaluated using the criteria listed in Table 2. To provide a relative illustration of impact severity, it is useful to assign numerical or relative descriptors to the impact intensity and receptor sensitivity for each potential impact. Each is assigned a numerical descriptor of 1, 2, 3, or 4, equivalent to very low, low, medium or high. The severity of impact was then indicated by the product of the two numerical descriptors, with severity being described as negligible, minor, moderate or major. This is a qualitative method designed to provide a broad ranking of the different impacts of a project. Illustrations of the types of impact that were assigned the different grades of severity are given in Table 2.

Table 1: Classification of impact evaluation

S.N	Classification	Description
1	Extent	Evaluation of the area of occurrence/influence by the impact on the subject environment; whether the impact will occur on site, in a limited area (within 2 km radius of the site); locally (within 5 km radius of the site); regionally (district wide, nationally or internationally).
2	Persistence/Duration:	Evaluation of the duration of impact on the subject environment, whether the impact was temporary (<1 year); short term (1 – 5 years); medium term (5 – 10 years); long term (>10); or permanent.
3	Social Context / Sensitivity or Potential for Stakeholder Conflict:	Assessment of the impacts for sensitive receptors in terms of ecological, social sensitivity and such things as rare and endangered species, unusual and vulnerable environments, architecture, social or cultural setting, major potential for stakeholder conflicts. The sensitivity classification is shown below: High sensitivity: Entire community displacement, destruction of world heritage and important cultural sites, large scale stakeholder conflict, etc. Medium sensitivity: Displacement of some households, moderate level of stakeholder concern Low sensitivity: No displacements, no potential for stakeholder conflict.
4	Regulatory and Legal Compliance:	Evaluation of the impact against Local and International legislative requirements. High: Prohibition terms for specific activities/emissions. Major breach of regulatory requirements resulting in potential prosecution or significant project approval delays. Medium: Potential breach of specific regulatory consent limits resulting in non-compliance. Low: No breach of specific regulatory consent limits anticipated.
5	Overall Impact rating (Severity):	Using a combination of the above criteria, the overall severity of the impact was assigned a rating Severe, Substantial, Moderate, Minor and negligible. Refer to Table 2 for broad categories of impact for each rating. Note: These are just guidelines that will constitute professional judgment required in each individual case.

Impact significance is determined from an impact significance matrix (Table 2) which compares severity of the impact with probability of its occurrence. Impact significance criteria are as follows:

- **Very High (VH) and High (H):** These denote that the impact is unacceptable and further mitigation measures must be implemented to reduce the significance. Shaded red in the Table 2.
- **Medium (M):** Impacts in this region are considered tolerable but efforts must be made to reduce the impact to levels that are as low as reasonably practical. Shaded orange in the impact significance matrix.
- **Very Low (VL) and Low (L):** Impacts in this region are considered acceptable. Shaded yellow in the impact significance matrix.

Table 2: Determination of impact severity/Sensitivity of receptor

		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low 1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

Finally, the magnitude and significance level of the identified impacts will be evaluated as major, high, medium or low significance impacts.

Step 8-Environmental Mitigation and Benefit Enhancing Measures: Based on the impact assessment feasible and cost-effective mitigating and benefit enhancement measures that may reduce potentially significant adverse environmental impacts to acceptable levels were recommended under this step.

Step 9-Environmental Management and Monitoring Plan: It will be necessary to monitor and audit project development and operation. Monitoring will provide the information necessary for feedback into the environmental management process and will assist in identifying where additional mitigation effort or where alteration to the adopted management approach may be required.

The monitoring plan describes the various environmental management strategies and generic procedures for their implementation. Further, it identifies the management roles and responsibilities for ensuring that monitoring is undertaken and that the results are analysed, and any necessary amendments are identified and implemented in a timely manner.

2 Project Description

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 spill overs 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

Ethiopia will serve as a public health Centre of Excellence for East Africa in multiple ways

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; (iv) equipping and furnishing 8 Biosecurity Level 2 (BSL-2) district laboratories already constructed by the Global Fund; 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.

- **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) analyzing 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 Centre 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.

2.3 Location of Project Site

The proposed Reference Laboratory project is located in Addis Ababa, Capital City of Ethiopia. It is specifically located within the campus premises of the Ethiopian Public Health Institute (EPHI) which is found in Gullele Sub City, Woreda 08, on Swaziland Street. Addis Ababa is constituted of ten sub cities and Gulele sub-city is situated in the Northern part of the Capital City. It is bordered by Oromiya Special Zone to the North, Kolfe Keranyo sub city to the west, Addis ketema and Arada sub cities to the south, and Yeka sub city to the east respectively.

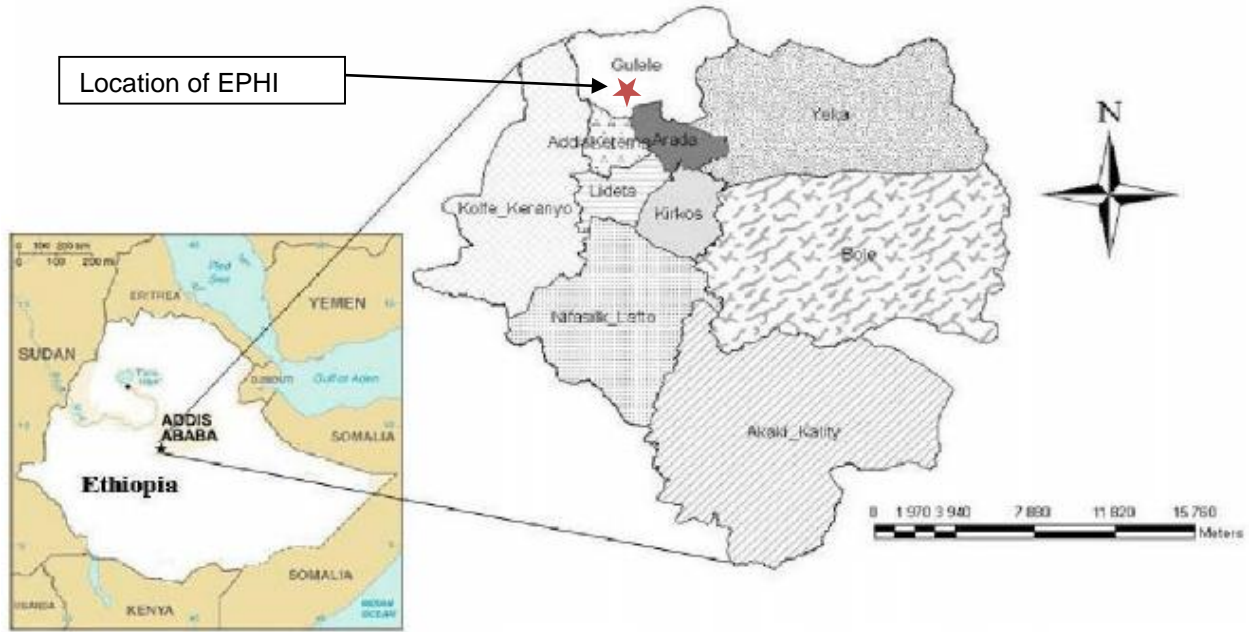


Figure 3: Location of Project Site

The geographical coordinates within which the proposed BSL-3 Reference Laboratory project would lie in the EPHI campus are given in table 3 below

Table 3: UTM Coordinates of the BSL-3 Laboratory Project Site in EPHI

	Coordinate	
	X-Coordinate	Y-Coordinate
1	0470273	0999830
2	0470248	0999928
3	0470199	0999919
4	0470174	0999878

The EPHI Campus is approximately 80,000 m² in area (Figure 4). There is a relatively large unutilized space available for development, most of which is covered by indigenous trees towards the Centre of the campus and tall eucalyptus trees along the southern perimeter. A small portion of the site designated for the development of the proposed BSL 3 NRL is currently occupied by G+0 office buildings of EPHI which will be demolished and cleared. EPHI campus is surrounded by mixed residential and business areas.

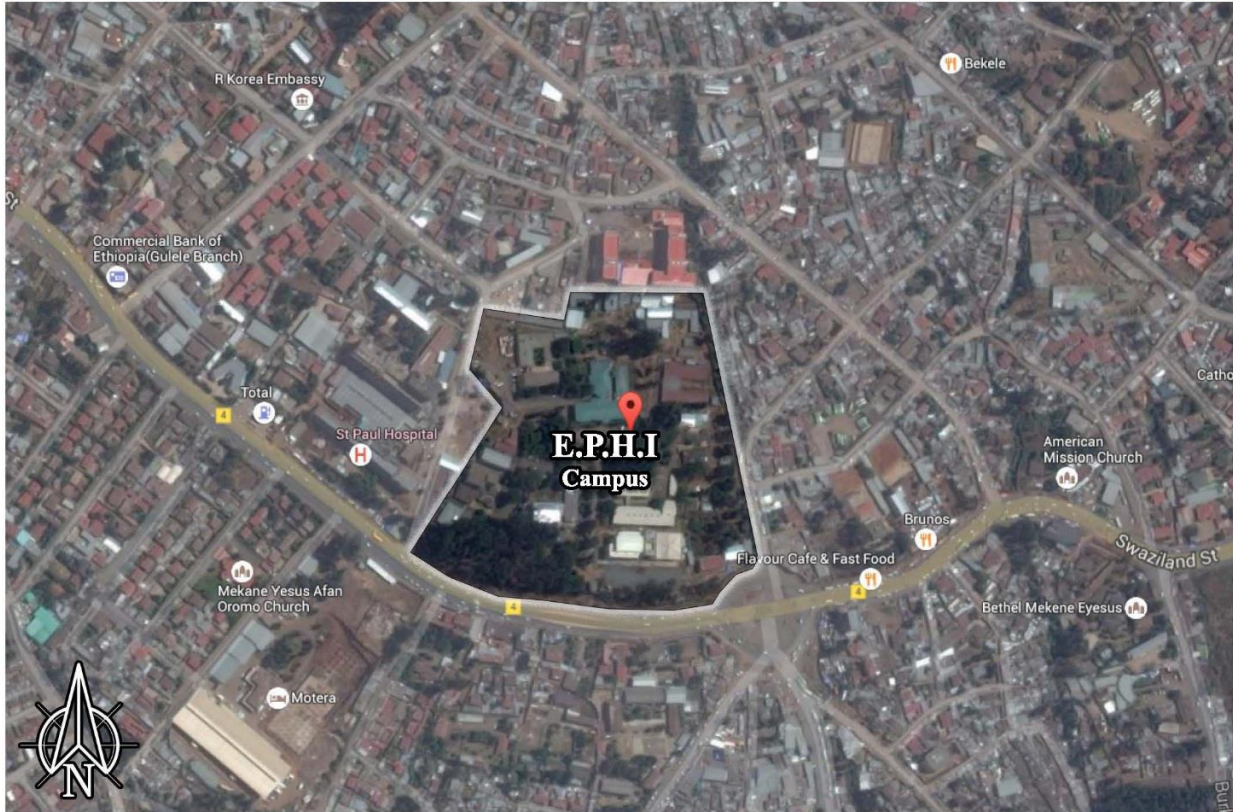


Figure 4: Google Earth Map of EPHI campus and its surroundings.

2.3.1 Description of the proposed BSL-3 Reference Laboratory Complex Building Development Project

The proposed BSL 3 National Reference Laboratory (NRL) building complex would be designed to lie on 1,700m² area. In conformity with the city master plan, the proposed NRL building will be a 7-story building (G+6) that fulfils the minimum requirements for height of buildings in the designated area. The G+6 NRL building will have a total gross floor area of 12,000m², consisting of 8000m² of Laboratory spaces and 4,000m² of Laboratory Office spaces, including related support spaces. The proposed NRL building would be divided into two main blocks with a connecting section. A large block accommodates the main laboratory spaces and the second and smaller block accommodates Laboratory Offices. The central connecting section houses common facilities like stairs, elevators, toilets, small conference rooms and pantry. All blocks are connected on every floor. Shared Common Equipment rooms will be provided on each laboratory floor to facilitate efficient use of shared or infrequently used equipment. All Main Laboratory and Laboratory Office Spaces are arranged along a double loaded corridor. All Laboratory traffic is

separated from the general traffic, allowing Laboratory professionals to travel back and forth between Main laboratory spaces and Laboratory Support spaces without having to cross public areas.

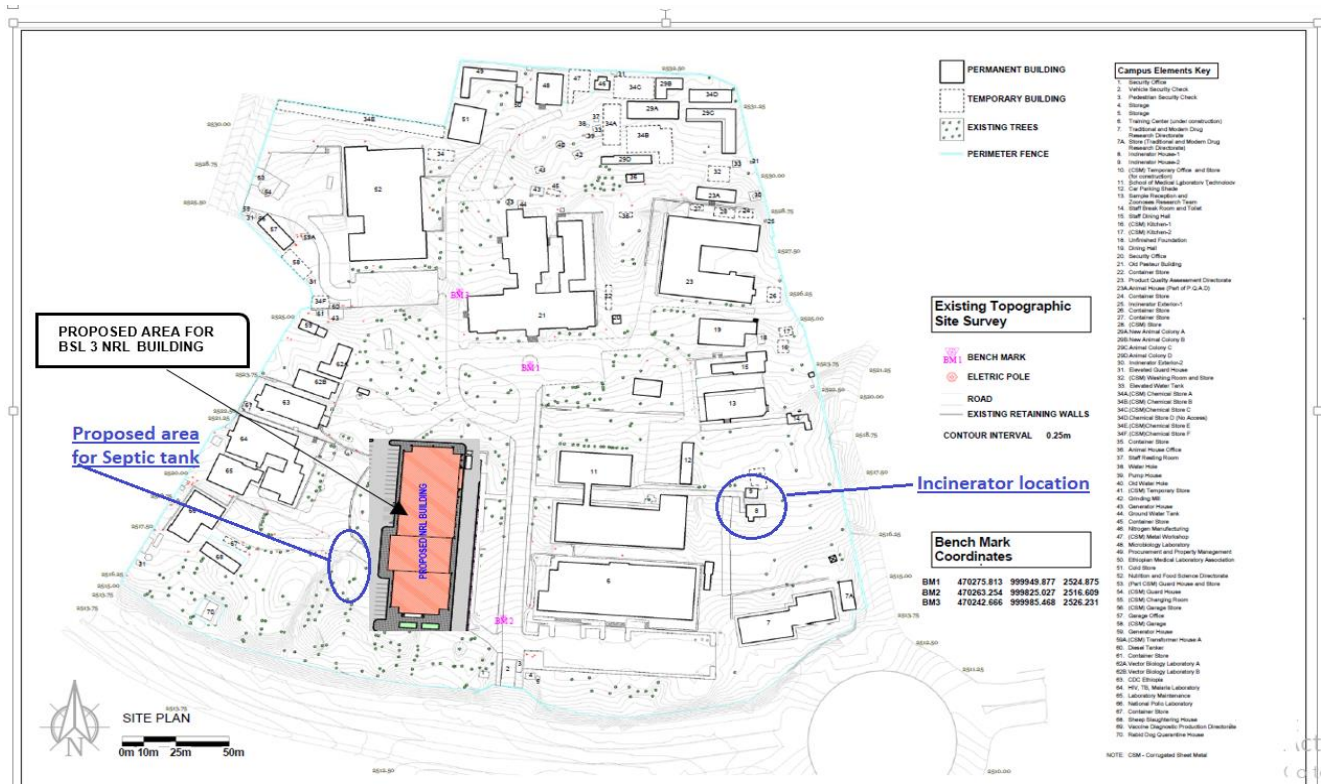


Figure 5: Site map showing the location of the BSL-3 NRL complex and associated facilities at EPHI

The design and shape of the NRL building has taken into consideration the maximum and minimum widths of typical laboratory and office spaces as well as the surrounding access roads and parking. The Design of the NRL would also allow for inline, continuous expansion of Laboratory, Laboratory Office Space and BSL-3 spaces. Provisions for parking, sidewalk access, roadway access as well as green area allocation were carefully considered in the design.

The Parking area for the proposed project is proposed to be in front of the NRL building, on the South side facing the main road, with direct access from the central axis. This double-sided parking area will act as a buffer zone from the noisy street. The main entrance of the NRL is proposed to be on the southeast corner of the building. The delivery and service access of the proposed NRL building is recommended to be on the northwest corner of the building, facing north. This location

will place it on the opposite side from the NRL building's main entrance, which will help to separate the two functions.

The NRL building will consist of BSL-3 laboratory suite, BSL-2 laboratory space, General Laboratory support facilities, Proficiency Testing Panel Production Centre (PTPC), Biobank Centre, Central Warehouse and a laboratory medical equipment maintenance Centre. Design of these facilities have based in part on the types of work that will occur in each Laboratory and the inherent risks associated with that work. The design of the laboratories has followed the principles of biosafety and biosecurity. Biosafety is ensured by introducing various design criteria of laboratory control and containment, through laboratory design and access restrictions, use of containment equipment, and safe methods of managing infectious materials in a laboratory setting. On the other hand, in order to ensure biosecurity, the project envisaged development of strict procedures for 'securing' or limiting access to the facilities, research materials and information during operational phases.

BSL-3 Laboratory: Pathogens worked within this laboratory have high individual risk, and generally low community risk. Generally, they are pathogens that can cause serious human or animal disease but do not ordinarily spread from one infected individual to another. All work is performed in bio-contained environments using appropriate engineering controls. Facility and design requirements generally included all the requirements contained in the BSL-2 laboratory with the addition of the following:

- Laboratory will be separated from areas that are open to unrestricted traffic flow within the building. Laboratory access is restricted.
- All windows in the laboratory will be sealed.
- Access to the laboratory is through two self-closing doors. A clothing change room ante-room will be included in the passageway between the two self-closing doors.
- Showers will be installed to be used when zoonotic risk group 3 pathogens are being used.
- The sink will be hands free or automatically operated. It would be located near the exit door.
- Spaces around the doors and ventilation openings should be capable of being sealed to facilitate space decontamination.

- Walls would be constructed to produce a sealed smooth finish that can be easily cleaned and decontaminated. Ceilings would be constructed sealed and finished in the same general manner as walls.

A ducted ventilation system that provide sustained directional airflow by drawing air into the laboratory from clean areas toward potentially contaminated areas

Diagnostic Laboratory (BSL-2): These labs are generally designed according to CDC's BMBL recommended design criteria for BSL-2 laboratories. The agents used in these laboratories have moderate individual risk and low community risk. It is usually a pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventative measures are available and their risk of spread of infection is limited. Processes that include the generation of aerosols should be conducted in primary containment such as biological safety cabinets. The Chemical Laboratories benches and other furniture will be installed based on the design layout. The floors, walls and working services would be designed to withstand accidental spills of the chemicals used in the laboratory. In addition, where laboratory fume hoods should be installed they should be located away from activities or facilities. Floors would be cove up walls and cabinets to ensure spills cannot penetrate underneath floors/cabinets. Facility design criteria/requirements generally included in the proposed NRL project consists of:

- Lockable self-closing doors with windows for viewing the occupants.
- Sinks for hand washing would be available
- The laboratory is designed so that it can be easily cleaned. Walls would be painted with washable, hard non-porous paints.
- Bench tops would be impervious to water, resistant to heat and any chemicals that may be used in the laboratory.
- Single-pass inward directional airflow is recommended.
- Biological Safety Cabinets (BSC) would be installed so fluctuations of room air supply and exhaust do not interfere with proper operations.
- A method for decontaminating all laboratory waste would be available within the facility
- An eye wash station shall be readily available or centrally located in the corridors

Proficiency Testing Panel Production Centre (PTPC): The PTPC will produce PT samples for Microbiology, Hematology, Parasitology, HIV Viral Load, HIV Early Infant Diagnosis (EID), serological tests, biochemistry, blood transfusion, immunological tests, mycology, and other samples. The PTPC will characterize samples, store, and transport and distribute to BSL 2 laboratories as well as preparing report and providing feedback to participant laboratories. The agents used in the PTPC have moderate individual risk and low community risk. It is usually a pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. The exposures may cause serious infection, but effective treatment and preventative measures are available and their risk of spread of infection is limited. Processes that include the generation of aerosols should be conducted in primary containment such as biological safety cabinets. The PTPC generally designed like BSL 2 laboratory that recommended by CDC's BMBL recommended design criteria for BSL-2 laboratories. The PTPC benches and other furniture will be installed based on the design layout. The floors, walls and working services would be designed to withstand accidental spills of the chemicals used in the laboratory. Floors would be cove up walls and cabinets to ensure spills cannot penetrate underneath floors/cabinets.

PTPC facility design criteria/requirements generally included in the proposed NRL project consists of:

- Lockable self-closing doors with windows for viewing the occupants.
- Sinks for hand washing would be available
- The Centre is designed so that it can be easily cleaned. Walls would be painted with washable, hard non-porous paints.
- Bench tops would be impervious to water, resistant to heat and any chemicals that may be used in the laboratory.
- A method for decontaminating all laboratory waste would be available within the facility
- An eye wash station shall be readily available or centrally located in the corridors.
- Single-pass inward directional airflow is recommended.
- A method for decontaminating all laboratory waste would be available within the facility
- An eye wash station shall be readily available or centrally located in the corridors.
- Furniture would be able to support anticipated loads and uses. Bench tops would be impervious to water, resistant to heat and any chemicals that may be used in the laboratory.

In addition, chairs used in the biobank work would be covered with nonporous easily cleanable material.

Biobank Centre: EPHI critically needs to establish a biobank that meet international standard. The planned biobank stores leftover specimens with full information collected from health facilities. The biobank infrastructure and storage system depend on the type of material being stored, the required storage conditions, the anticipated period of storage, and the intended use of the materials, and the storage system is fundamental to maintaining high sample quality. The data and databases related to biospecimen annotation, quality, storage location, and use, are important attributes of biobank infrastructure. Biospecimen storage infrastructure will have two types of storage systems are used for biospecimen storage: ultra-low-temperature (or low-temperature) storage systems and ambient- temperature storage systems. “Ultra-low temperature” can be defined as temperatures below $-80\text{ }^{\circ}\text{C}$ (e.g. LN2), and “low temperature” as temperatures between $0\text{ }^{\circ}\text{C}$ and $-80\text{ }^{\circ}\text{C}$.

Liquid nitrogen storage: Liquid nitrogen (LN2) facilities contain LN2 in liquid phase tanks and vapour-phase containers. Cryogenic storage using LN2 is an effective long-term storage system, because its extreme ultra-low temperatures slow down most biological, chemical, and physical reactions that may cause biospecimens to deteriorate.

Mechanical freezers storage: Mechanical freezers are used for a variety of storage systems with temperatures ranging from low temperature to ultra-low-temperature conditions, including $-20\text{ }^{\circ}\text{C}$, $-70\text{ }^{\circ}\text{C}$ to $-80\text{ }^{\circ}\text{C}$, and $-150\text{ }^{\circ}\text{C}$, and come in a wide range of sizes and configurations.

Refrigerators: Refrigerators would be used for samples that can be maintained at ambient temperature. However, the longevity of biospecimens being stored is enhanced if they are stored below ambient temperature, due to biomolecular degradation that can occur at high ambient temperatures.

Ambient-temperature storage: the other methods for to be used in a biobank is a specific biological storage matrix that would be used for long term maintenance of some biological components at room temperature. Formalin-, PAXgene-, or ethanol-fixed, paraffin- embedded tissues and lyophilized samples can be stored at ambient temperatures. Dried samples, such as blood spots on filter paper, can be stored at ambient temperature.

The benches and other furniture will be installed based on the design layout. The floors, walls and working services would be designed to withstand accidental spills of the chemicals used in the

biobank. Floors would be cove up walls and cabinets to ensure spills cannot penetrate underneath floors/cabinets.

Facility design criteria/requirements for biobank generally included in the proposed NRL project consists of:

- Lockable self-closing doors with windows for viewing the occupants.
- Sinks for hand washing would be available
- The biobank is designed so that it can be easily cleaned. Walls would be painted with washable, hard non-porous paints.
- Bench tops would be impervious to water, resistant to heat and any chemicals that may be used in the laboratory.
- Single-pass inward directional airflow is recommended.
- Lockable self-closing doors with windows for viewing the occupants.
- Sinks for hand washing would be available
- Finishes and surfaces that can be easily cleaned and will not harbour potential contamination if spills were to occur like carpet and cloth.
- Spaces between benches, freezer/refrigerators, and equipment would be accessible for cleaning.

Central Warehouse: The warehouse is an auxiliary facility which will be part of the BSL 3 laboratory. Its main utility is to provide and maintain sustainable supply and storage of reagents, chemicals and consumables bound to activities of the BSL 3 laboratory. The furniture will be installed based on the design layout. The floors, walls and working services would be designed to withstand accidental spills of the chemicals stored. Emergency shower, an eye wash station, fire alarm, and other security devices would be readily available and centrally located in the corridors. Spaces between shelves, tables benches, freezer/refrigerators, and equipment would be accessible for cleaning. All building materials would be chemical resistance, especially towards the stored chemicals. In particular, the flooring will be damp- and chemical-proof. Moreover, in order to avoid contact with hazardous substances all surfaces would be easy to clean. At the same time a skid-proof flooring will prevent occupational accidents due to falls. Storage facilities would also preferably be constructed of non-combustible materials so as to avoid dissemination of hazardous chemicals, should a fire threaten the storage facility.

The central warehouse is allowed only to authorised personnel. Therefore, constructive arrangements would be made in order to control access. Furthermore, access to the facility and its alleyways will be large enough and designed according to the activities carried out (use of handling equipment, for instance). In case of emergency, the rescue teams would also be able to access the storage facility quickly. Thus, stairs and steps close to the entrance of the facility would be avoided. There would be emergency exits on the facility size and configuration. Escape doors would be designed in such a way that they open to the outside and that they would be opened easily from the inside without the use of any key. An eye wash station, first aid kits fire alarm, and other security devices would be readily available and centrally located in the corridors

Laboratory medical equipment maintenance Centre: equipment maintenance Centre is an auxiliary facility which will be part of the BSL 3 laboratory. Its main utility is to provide maintenance and calibration services for BSL 3 laboratory medical equipment and NRL for the sustainable laboratory services without interruption of the services. The floors, walls and working services would be designed to withstand accidental spills of the chemicals stored and well ventilation. Spaces between shelves, tables benches, maintenance and calibration equipment, and equipment would be accessible for maintenance and cleaning. Enough space for storage of spare parts and tools. An eye wash station, first aid kits fire alarm, and other security devices would be readily available and centrally located in the corridors.

An access to the facility and its alleyways will be large enough and designed according to the activities carried out (use of handling equipment, for instance). In case of emergency, the rescue teams would also be able to access the storage facility quickly. Thus, stairs and steps close to the entrance of the facility would be avoided. There would be emergency exits on the facility size and configuration. Escape doors would be designed in such a way that they open to the outside and that they would be opened easily from the inside without the use of any key.

2.4 Design Requirement of the proposed BSL 3 Laboratory and operation

Specifications

The BSL-3 laboratory which is going to be built at EPHI would be designed and operated in accordance with guidance for BSL-3 laboratories established by reputable international organizations (CDC 1999, NIH 2001, WHO 2004). The laboratory will be tested for verification

that the design and operational parameters have been met prior to operation. Annual verification of BSL-3 laboratory is recommended by the WHO biosafety manual and CDC BMBL and the laboratory layout will have the arrangement depicted in the figure below. Hence, the proposed BSL3 lab will be annually verified using the checklist in Annex 5.

2.4.1 General design and safety requirements for the BSL3 lab

The BSL3 laboratory will consist of an **anteroom** and laboratory rooms. It will have gas-impermeable walls, ceilings and floors. Air gaps under doors would be acceptable for directional airflow. If door gaps are sealed, the laboratory must not leak gaseous decontamination materials. The BSL3 laboratory will be designed for ease of maintenance, so that access to critical mechanical equipment (ventilation ducts, fans, piping, etc.) is outside containment. The laboratory will consist of high-quality room construction with special consideration given to joints, finishes and penetrations. There will be a room for large equipment decontamination.

The room will be capable of being sealed for decontamination with gaseous paraformaldehyde and must have a connection to the HVAC exhaust system. All shutoffs (steam, water, natural gas) will be external to containment. All tall and/or heavy fixtures and equipment (e.g. biological safety cabinets, autoclaves, freezers, incubators, etc.) will be fitted with a seismic anchoring system/device engineered to withstand earthquake stresses equal to 7.0 on the Richter scale. Work surfaces, floors, walls and ceilings will be designed, constructed and finished to facilitate easy cleaning and decontamination. The laboratory will be located away from public areas and corridors used by laboratory personnel who do not work in the BSL-3 laboratory. The BSL3 must pass third-party inspection and tests to verify that design and operational parameters have been met. Specific design and operation requirements for the lab are outlined below.

2.4.2 Anteroom Specifications

The anteroom of the lab will have two doors to access the laboratory. Anteroom doors will be interlocked or alarmed, so only one door may be opened at a time or placed sufficiently apart so that one person cannot open both doors at the same time. Air gaps under doors would be acceptable for directional airflow, i.e., doors are perpendicular to each other and anteroom is of sufficient size. A manual override would be provided for emergency exit. The anteroom will have ventilation separate from the laboratory to maintain the containment envelope in the event of a ventilation

failure. The anteroom will be large enough to provide storage for clean gowns, laboratory coats, or uniforms that must be donned before entry and be removed before leaving the suite. It also provides space for a log book, wall calendar, and a laundry hamper. The anteroom will have communication capabilities installed. Biohazard warning symbol, list of personnel authorized, and access rules will be posted on or near the door that can be easily noticeable.

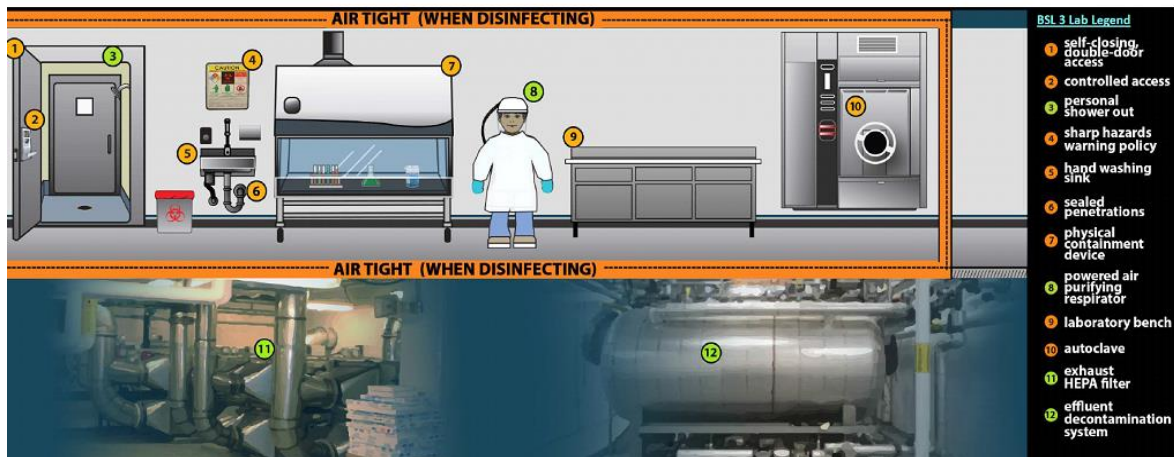
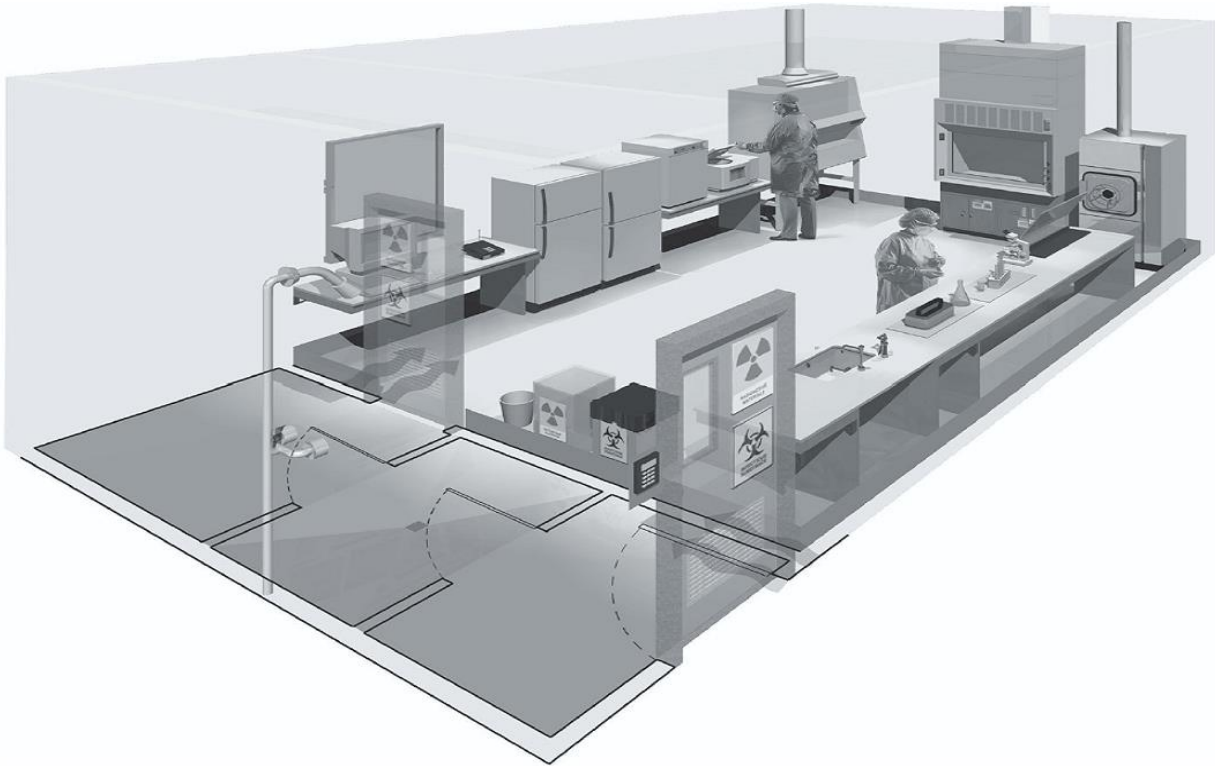


Figure 6: Proposed BSL 3 Laboratory layout adopted from WHO and CDC

2.4.3 Specifications for floors, walls and ceilings

The BSL-3 lab at EPHI will be constructed using concrete footing and stem walls with concrete slab-on-grade floors. Walls would be steel stud framed and roof construction would consist of metal decking over steel bar joists. The exterior walls would have an application of stucco and the painting of the building would be visually consistent with surrounding structures.

The lab floors will be impermeable to liquids, monolithic/seamless, or have welded seams. Floors must be easily cleaned, with chemical-resistant flooring (vinyl, or epoxy with fiberglass reinforcement) with a slip-resistant, smooth, hard finish. For monolithic floors, either a 100-mm-high, readily cleanable, integrally coved sheet flooring base, or a readily cleanable, 100-mm-high, vinyl or rubber base should be used. For epoxy floors, if silicone sealants are used for penetrations, the silicone must be applied after the epoxy has been installed. Floors would be monolithic and slip-resistant.

The walls of the lab must be durable, washable and resistant to detergents/disinfectants (masonry, gypsum board, fiberglass-reinforced plastic, etc.). Walls will also be painted with durable glossy acrylic or epoxy paint. For epoxy paint, if silicone sealants are used for penetrations, the silicone must be applied after the epoxy has been installed. Wall/ceiling penetrations will be kept to a minimum and sealed with non-rigid, non-shrinking silicone or latex sealant. For fire rated walls, sealant will be applied before stopping.

The ceiling of the BSL3 lab must be washable and resistant to detergents/disinfectants. Ceiling has to be painted with durable glossy acrylic or epoxy paint. If silicone sealants are used, the silicone will be applied after the epoxy. The ceiling must be of monolithic construction (i.e., gypsum board, not removable tiles). The ceiling must be high enough over Class II A2 biological safety cabinets (BSCs) to allow a canopy/thimble connection or the opening of canopy/thimble door(s). Ceiling height would be at least 10 feet to allow 14 inches of clearance above BSCs. All penetrations in floors, walls and ceiling surfaces would be sealed, or capable of being sealed to facilitate disinfection, to aid in maintaining appropriate ventilation system air pressures and to keep pests out.

Justification: Due to the highly pathogenic nature of the microorganisms frequently encountered in BSL3 laboratories, the efficacy of disinfection and decontamination procedures must be ensured without compromising the integrity of the facility. Surfaces that absorb water or degrade in the presence of chemical disinfectants are not suitable for an environment that will be repeatedly

exposed to both. Sealed surfaces and floor coving are recommended to reduce the number of cracks or crevices that may harbour microorganisms during application of a disinfectant or decontaminant.

2.4.3.1 Doors

Lab doors to be installed for this lab would be self-closing and lockable. Doors need to be open inward slide open. If sliders are used, they must be made of safety glass and a trackless design should be considered. Door between anteroom and corridor must have door sweep for pest control. Door openings should be sized to allow the passage of large equipment. Wall-door frame connection would be made airtight at time of frame installation. Doors and frames will be of solid finish construction, with the required fire ratings and include panic-hardware, hardware appropriate for high-use and kick plates. Doors would be coated metal which is chemical resistant. Methods for restricting access to only those individuals with demonstrated need, proper clearance, and training must be in place. Notices will be posted outside the first door to notify potential entrants of the hazards contained within and measures they must take to protect themselves.

Justification: The risk of potential exposure in high containment spaces and the regulatory requirements for access to Select Agent spaces require that only those individuals with demonstrated need and proper preparation be allowed access to high containment spaces. Interlocking double-door access is necessary to ensure that, at no time, is the interior of the laboratory exposed to any common area.

2.4.3.2 Windows

Windows (safety glass, permanently closed, sealed with silicone or latex sealant) would be installed so that the interior of the adjacent room, except change rooms and restrooms, is visible. Windows must not allow viewing from public areas. Interior sills will be sloped away from windows for ease of cleaning or to minimize dust collection.

Justification: To maintain proper pressure differential and directional airflow, to prevent egress of aerosols, particularly during space decontamination, to the surrounding spaces or environment, and to assist with pest control.

2.4.4 Eyewash/Safety Shower

An emergency eyewash will be in each BSL-3 room. A combination emergency eyewash/safety shower unit must be in near proximity to places if personnel are exposed to splash hazards (determined during programming). Emergency eyewash and emergency eyewash/safety shower units would be sited and installed.

Justification: Numerous microorganisms are infectious if exposed to the mucous membranes around the eye. Therefore, eyes shall be flushed thoroughly after splashes and exposures to the eyes.

Plumbing

All penetrations must be perpendicular to the surface and must be sealed to be gas-tight. Penetrations must also be sealed with nonrigid, non-shrinking, silicone or latex sealant. For fire-rated walls, sealant will be applied before stopping. All pipes into the BSL-3 laboratories would be secured to prevent movement. Fixtures must be resistant to corrosion of bleach and other disinfectants. Back-flow prevention devices will be installed on all faucets (including industrial water). All pipes will be identified by using labels and tags. Water supply control will be located outside the containment area. Plumbing should discharge directly to a sanitary sewer.

2.4.5 Sinks

Hand washing sinks in the lab will be available in each room near exits. Sinks will be hands-free. Infrared sensors are preferable but may not be suitable for all laboratories. In cases where infrared sensors cannot be used, knee-operated sinks are preferable to foot-operated. Each sink will have chemical-resistant traps (for disinfectants), a coved backsplash, a hot-cold water and pre-mixing faucet. Hand washing sink will be accompanied by a paper-towel dispenser and a hands-free soap dispenser mounted within easy reach.

Justification: Numerous pathogenic organisms can be transferred by hand contact to mucous membranes or other surfaces in the laboratory. It is extremely important to wash hands often and before leaving the laboratory. For the latter reason, the sink shall be located close to the egress.

2.4.6 Autoclave

An autoclave in the lab will be equipped with interlocked doors. Decontamination cycles would be determined during programming; gravity and liquid cycles are typical. Appropriate autoclave

size should be determined prior to purchase. The body of the autoclave will be located outside containment to provide easy access for maintenance. Enough space adjacent to the contaminated (input) door must be present for waste collection. Control panels should be located internal and external to containment. Bioseals or other equivalent means would be used to create a seal at the wall. The floor under the autoclave would be monolithic, seamless, or heat-sealed, coved and water-tight. Floor penetrations, if essential, would have a water and gas-tight seal at the monolithic floor. Walls and hard ceiling will have epoxy paint. Exposed pipes would be insulated. The autoclave should be seismically anchored. A curbed corrosion-resistant basin would be installed to prevent leakage. A canopy hood will be provided over the exit door of the autoclave to contain heat and steam. The installation will be signed off by a professional engineer. The autoclave room must have a minimum of 10 air changes per hour.

2.4.7 Fire Safety and alarms

Fire alarms must be clearly audible above ambient noise. A wall-mounted ABC Dry Chemical fire extinguisher must be mounted near the exit door of the anteroom. Laboratory-safe refrigerators or metal flammable cabinets will be used to store flammable/combustible materials. Alarms are provided for: fire hazard, ventilation failure, differential pressures below 0.05" wg, -80°C ultra-cold freezers and intrusion detection systems. Alarms will be connected to the building control system and to campus public safety department. Alarms should be audible and visible throughout the laboratory. Alarms would be differentiated from each other so that each can be easily identified. Alarms will be on UPS power.

2.4.8 Vacuum System/Pump

Vacuum lines will be protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters will be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and HEPA filters). If an individual vacuum pump is used, it would be located in the laboratory. Noise and maintenance issues would also be addressed.

2.4.9 Electrical requirements

In this BSL3 lab, an emergency power will be provided for HVAC (including controls), alarms, emergency lighting, biological safety cabinets, storage freezers and incubators. UPS power would be provided to alarms, and when possible, to biological safety cabinets. An independent circuit

would be provided for each biological safety cabinet. Wall/ceiling penetrations would be kept to a minimum and will be sealed with non-rigid, non-shrinking silicone or latex sealant. For fire-rated walls, sealant will be applied before stopping. Junction boxes would be cast and/or sealed airtight (e.g. closed cell foam compatible with gaseous paraformaldehyde). Light fixtures are surface or pendant-mounted. Circuit breakers will be located outside containment and are labelled.

2.10 Heating, Ventilation and Air Conditioning (HVAC) System requirements

The HVAC system would be Constant Air Volume (CAV). Variable Air Volume (VAV) is not recommended. Electronic direct digital controls are used to manage the system. Recirculation of exhaust air will not be allowed. A dedicated exhaust system is required. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Locating the exhaust stacks on the roof and discharging upward at a velocity greater than 3,000 fpm is recommended. An exhaust HEPA is required (see HEPA filter section). The need for a redundant exhaust fan would be determined by users, to allow continuing work. Air supply and exhaust system capacity should be $\geq 125\%$ of the laboratory's requirements to provide for future adaptability and flexibility. The HVAC system creates directional airflow drawing air from rooms/areas of low hazard into rooms/areas of higher hazard. Inward directional airflow will be maintained by providing 15% more flow of exhaust airflow than supply air, and sufficient to maintain the differential pressure between rooms in 0.05-0.20" Wg range. The air balance accommodates biological safety cabinet canopy/thimble connection or Class II type B2 cabinet exhausts requirements. Inward directional airflow will be verified before entry. Devices to indicate/confirm directional airflow into the laboratory (e.g., 0 - 0.20" Wg magnehelic gauges, digital differential pressure monitors or both) will be installed. If exhaust system fails, the lab must not become positively pressured. Whenever possible, the supply and exhaust fans will be electrically interlocked. Exhaust ductwork will not be positively pressurized.

Supply and exhaust dampers would be gas-tight and closable from outside the facility to facilitate decontamination with gaseous paraformaldehyde. Local visual and audible ventilation system failure alarms are required for laboratory personnel. Air supply diffusers will be located so that airflow at the biological safety cabinet face is unaffected (laminar diffusers preferred). Ductwork would be located external to the laboratory; if exposed in the laboratory, ductwork is clear of walls to allow for cleaning, maintenance and leak testing. Ductwork will be gas-tight 316 stainless steel

up to the HEPA filter. All ducts will be constructed in a leak-tight manner with seams and joints usually welded airtight. The biosafety officer will determine if exhaust ductwork is to be welded. If the exhaust ductwork is welded, welded joints will be recommended for all connections except for the damper(s) (use flange and bolt connections for quick change-out in the future). Coil units (for supplemental cooling) should not impact cleaning or provide a breach of containment. Elbows will be limited whenever possible to reduce the amount of background noise generated.

Justifications: Recirculated air is not permitted to eliminate any possibility of potentially contaminated air entering other building spaces such as in the event of a failure in one of the containment systems. Negative air pressure between rooms produces the directional airflow necessary to contain potentially contaminated aerosols, 0.05" WG is typically within the operating range of most HVAC components and sensors and provides containment during common events such as doors opening and personnel ingress/egress. Positive pressure ductwork inside occupied spaces is not permitted to eliminate any possibility of potentially contaminated air entering building spaces in the event of a breach or failure in the ductwork. To maintain directional airflow under failure scenarios, control valves must be in place to compensate for changing system pressures. With airflow offset control, doors must be designed to allow air to flow into room to maintain directional airflow. As an option, if doors are too tight barometric damper in door or wall of room can be provided.

2.11 HEPA filter

The HEPA filters in this lab will be "bag-in, bag-out," and the housing accommodates gas decontamination and filter testing (gas-tight dampers and housing). In order to facilitate filter change-out, the HEPA filter housings will not be more than five-feet high. When HEPA filters are installed, a magnehelic gauge or other pressure-monitoring device will be put in, with the display placed in the most accessible location that is practical to measure pressure drop across the filters. A HEPA could be required on the autoclave exhaust, ultracentrifuge vent and sewer vent. HEPA filters must comply with DOE-STD-3020-97 (or latest edition). Arrangements will be made to permit periodic leak testing of exhaust system HEPA filters. The system also needs comply with ASME AG-1.

Justifications: Enhanced engineering controls, such as HEPA-filtered exhaust, are necessary to prepare the space for the potential need in future research. Providing HEPA-filtered exhaust (or

the capability to do so, e.g. installing HEPA filter housings but not using HEPA filters until required) affords greater flexibility and adaptability of the BSL3 laboratory spaces.

2.12 Laboratory Furniture and Casework

Furniture and casework in the lab will be sturdy and capable of supporting anticipated loading and uses. In addition, they will be spaced so that areas around and under benches, cabinets and equipment are accessible for cleaning. Benchtops will be impervious to water and resistant to acids, alkalis, organic solvents and moderate heat. They will also have marine/drip edging for spill control. For future flexibility, modular mobile casework will be used. Ergonomic considerations will be made while designing laboratory furniture and casework (e.g., adjustable work-surface heights, selection of biological safety cabinets, adequate knee clearances for seated work, adequate toe clearances for standing work, wall cabinet heights, etc.). Fixed casework, if used, will be sealed /caulked to the walls on installation to facilitate cleaning and prevent harbourage for vermin. If fixed casework is used, it would be installed before the coved flooring so that the coving can extend up toe-kicks. For storage, closed cabinets will be used rather than open shelving. Chairs and other furniture would be covered with a nonfabric material that can be easily decontaminated. Tall or movable cabinets/shelves would be seismically anchored. To facilitate cleaning, cabinets/shelves would be made to have angled tops or be built up to the ceiling.

Justification: Activities within the BSL3 laboratory could involve concurrent use of chemical solvents such as formaldehyde, phenol and ethanol as well as corrosives or other reactive chemicals. The laboratory bench or BSC work surface must be resistant to the chemical actions of these substances as well as disinfectants used to inactivate the organisms under study. Wooden or other porous or combustible bench tops are not appropriate because even finished wooden surfaces can absorb liquids or ignite in the event of a fire. Fiberglass is inappropriate since it can degrade in the presence of some chemicals; it also produces toxic smoke if burned. Laboratory furniture must not be absorbent so that it may be decontaminated effectively. Space must be left between furniture to allow for cleaning and maintenance of devices as required (i.e. biosafety cabinets).

2.13 Security

The EPHI BSL3 lab access controls will be provided to record entry and exit times and dates. Palm scan, proximity card, keypad entry with codes unique to each worker, cardkey or equivalent will

be used. Access to mechanical and support areas will be limited. Security measures will meet the requirements of the Select Agent Regulations if the facility is to be used for selecting agent work or storage. Security measures will meet the guidance set forth in the latest version of the CDC-NIH's Biosafety in Microbiological and Biomedical Laboratories.

2.5 Commissioning of the BSL3 lab

Commissioning of the BSL3 lab would be performed by a third party in the presence of the proposed BSL3 lab's Biosafety Officer. The biosafety officer will furnish checklists for the containment features to be evaluated, depending on the facility design. Initially, the lab needs to pass a series of inspections and tests to meet standards that have been predeveloped, authorized, and specified in the design and construction documents before biohazardous agents are used. These are in addition to the desired outcomes by the commissioning team identified prior to initiation of construction activities. A properly designed and constructed biocontainment facility, including its structural and mechanical safety systems, must meet predetermined performance criteria and be operational upon completion of construction.

The integrity of the critical components of the biological containment systems will be verified by the testing and certification requirements. Certification of the BSL3 lab, including structural components and safety systems, will be included as part of the overall commissioning processes normally undertaken to verify that the design and construction meet applicable standards, and that the facility can operate in accordance with the design intent. Commissioning testing must also be performed without degradation to the facility or mechanical system that is being tested. All equipment and materials would be tested/evaluated prior to installation; duplicate testing is recommended. BSCs will be certified in accordance with NSF 49 after the BSC is anchored in its final location. All HEPA filters will be tested to meet NSF 49 after installation. Integrity of seals will be demonstrated by visual inspection. The integrity of epoxy coatings may be tested using ASTM D4541 Standard Test Method for pull-off Strength of coatings using portable adhesion testers. Autoclave installation will be attested by the sign-off of a professional engineer. The autoclave will be tested to verify that it meets specified standards:

- Calibration of thermometers
- Calibration of clocks and timers

- Biological indicators are used to verify the autoclave's effectiveness

The ventilation system will be tested by:

- Ventilation ductwork and HEPA housings and must pass pressure-decay testing under ASHRAE SMACNA Standard 126-2000 (Method of Testing HVAC Air Ducts)
- Measurements of airflow at each supply and exhaust diffuser
- Smoke testing to visually verify limited turbulence at face of BSC
- Smoke testing to visually verify airflow from areas of low hazard to areas of higher hazard
- Verification that air system failure alarms (exhaust, supply, room pressure) function and annunciate properly
- Air balance report provided and verified by the biosafety officer

2.5.1 Qualification of the construction agency/contractor for the lab

Finding and hiring the right construction agency for the construction of BSL3 lab at EPHI is the key step for the success of the project. The construction agency with satisfactory qualification and expertise helps in making the containment laboratory functional and achieve standards of biosafety practices for safer working environments. The following essential qualification criteria will be considered when hiring a construction agency for the proposed BSL3 lab: (i) the minimum average annual turnover during the last three financial years (as per their audited balance sheets) must be adequate to make sure that agency would be able to complete the project. (ii) successful and timely completion of at least one similar project (construction, testing, commissioning and validation of BSL-3 laboratory) including civil, electrical, HVAC works, BMS, door interlocks, access control system, primary barrier containment equipment, decontamination system, etc. Additionally, the ability of construction agency for designing and planning, correct evaluation of architectural layout plans, men and material movement plans, zoning plans, specialized systems and services schemes, services and utilities schemes, laboratory commissioning and validation protocols, laboratory security protocols and integration of laboratory and equipment will be assessed.

2.5.2 Operation and Verification Procedures of the lab

The EPHI BSL-3 lab would be operated according to all guidance and requirements established by the CDC and NIH (CDC 1999), WHO, 2004, BMBL (2005). Prior to operating the BSL3 using select agents, the lab would be assessed by pertinent Ethiopian environmental regulatory organs at Ministry of Health and Environment Commission of Ethiopia to verify that the BSL3 meets

biosafety level requirements for working with the biological agent. The verification will be conducted using the detailed check list in Annex 5 (adopted from CDC). The lab will be functional only if it meets the minimum standards set by CDC. No select agents would be handled in the proposed BSL-3 laboratories without first obtaining approval from pertinent environmental and health regulatory organs in Ethiopia. Microorganisms that are not select agents would also be used in the BSL-3 laboratories but would still be handled according to CDC, WHO and NIH guidance and requirements. Risk analysis will be performed before any infectious microorganisms is handled in the BSL-3 lab in accordance with CDC, WHO guidance. Besides, the local medical community would be informed of the microorganisms to be handled in the BSL-3 laboratory and would be aware of the methods of identification and control of associated diseases.

Lab work associated with infectious microorganisms will be approved and authorized by EPHI management based on the following:

- Biological Weapons Convention Treaty (BWC 1972) permits defensive research for developing vaccines and protective equipment.
- Work Smart Standards, which include adopted standards from CDC (CDC 1999), NIH (2001) and, BMBL (2005), WHO.
- The EPHI Biosafety Committee, a diversified group of EPHI operational-level researchers and representatives from all EPHI-affected institutional and regulatory compliance organizations who are responsible for the first-level reviews of projects/microorganisms and provide recommendations.
- The lab would undergo a readiness review prior to start up to ensure that the infrastructure for safe operation is implemented and that the health and safety of workers, public and the environment is protected.
- Compliance of lab operation with a variety of non-governmental organizations that provide guidance for transportation of infectious agents including the *Dangerous Goods Regulations*, the *Infectious Substances Shipping Guidelines* of the International Air Transport Association (IATA 2001), and the *Guidelines for Safe Transport of Infectious Substances and Diagnostic Specimens* of the World Health Organization (WHO) (WHO 1997).

Ethiopian Public Health Institute would procure and avail personal protective equipment for the BSL3 employees to minimize occupational and safety risks. Appropriate PPE used by employees

entering the laboratories would include eye protection, gloves (in some cases the worker would be double-gloved), and disposable closed-front gown or clothing (including disposable booties and disposable cap). Air-purifying respirators might be worn as an additional safety measure for some tasks. Workers' hands would be washed with disinfectant immediately before and after putting gloves on or after any potential contamination with infectious agents. The BSL3 lab workers could shower after finishing their laboratory work upon removal of their PPE clothing if deemed necessary. Worker's hair would be kept short or secured away from the face and no skin would be exposed below the neck; workers would be required to wear socks, closed shoes, and long pants underneath the disposable coverings. Most of all materials used in the BSL-3 lab would be disposable, but some reusable laboratory apparatus, such as test tubes or culture dishes may be needed for some minor amount of sterile work. No open flames would be allowed within the BSCs. Work in the laboratories would be scheduled and planned to avoid conflicts within the laboratory areas. All workers in the BSL-3 laboratory areas would be informed of what other workers would be handling so that appropriate staging of work could occur. Open cultures would only be handled in BSCs. BSCs would be at negative pressure with respect to the room and the rest of the building. Airflow would always be directed away from the worker and into the BSC. Workers at EPHI BSL3 would be offered appropriate immunizations for the microorganisms being handled. They would also be tested for normal immunocompetency and would have medical treatment readily available in the event of an accidental exposure. No radiological material would be used or stored in the laboratory. To control vector populations, a pest program would be in place.

2.5.3 Sample Arrival and processing at the EPHI BSL-3

Sample shipments would only be received at the BSL-3 facility operating within the parameters specified in all established guidelines and requirements. The protocol for receiving and handling of samples would be worked out prior to receipt and reviewed and approved by the EPHI Biosafety Committee of the BSL3. All incoming packages (regardless of origination point) containing infectious agents would be packaged in DOT-approved packages. These packages could be about 6 to 8 inches (15 to 20 cm) in height and about 3-4 inches (8 to 10 cm) in cylinder diameter. All shipping containers would be made of plastic and samples would be double- or triple-contained. Transportation and interstate shipment of biomedical materials and import of select agents would be subject to the requirements of Ethiopian Environmental and Public Health regulations as well as best international practices. Strict chain-of-custody procedures for samples arriving at the EPHI

BSL3 lab receiving site would be followed. Due to the perishable nature of the samples at the BSL-3 facility, receiving and shipping of samples normally would only occur during weekday daylight hours and samples must be opened and used or restored (put in growth media) within 8 hours of arrival.

External packaging material from packages received at the lab would be inspected, removed, autoclaved, and disposed of according to waste handling procedures specified below. Samples would be stored in the BSL-3 laboratory within a locked freezer or refrigerator, according to the needs of the sample for preservation. Inventories of all samples and cultures would be kept. Samples and cultures would be identified by a numeric or alpha-numeric code rather than by the name of the microorganism or source. Sensitive information about samples and results would be maintained elsewhere at EPHI in a safe and secure manner in accordance with security requirements. The samples could also be immediately processed, in which case the materials would be placed directly into culture media (such as a liquid or semi-solid nutrient material or media). All preparations and manipulations of cultures or samples would only occur within a fully operating BSC.

Culture of Samples

For culturing, samples would be removed from their primary containers in a BSC a tube and flask. Plate containing a specific nutrient media would be inoculated with the sample to create a culture. All culture work would be completed and cleaned up within one work-shift (8 hours) except for materials being incubated. Culture and culture-storage containers would typically be made of plastic and always be double-contained. The culture container would be transferred to a temperature-controlled incubation chamber to grow the organisms (multiply the number of microorganisms) for a period lasting up to several days. Centrifugation of live, intact microorganisms would be conducted in sealed containers placed inside sealed tubes to minimize the potential for aerosolization of microbes or, if appropriate, centrifugation could be conducted inside a BSC. Cultured materials, which are sources for research materials, could be “lysed” (broken open) or killed (inactivated) by the addition of a variety of chemicals such as detergents or by using a chemical phenol. The lysed or killed cells and the culture media could be processed into biological material that would later be analysed by various research methods at various EPHI research laboratories, and potentially at other laboratories off-site. Following incubation (hours to

days), all cultured materials would be cleaned up within one work-shift (8 hours). Many cultures would be archived in small quantity and maintained in the ultra-freezers in each laboratory.

2.6 Waste management approaches and standards for the BSL-3 NRL

Complex

This section summarizes the waste management approaches and standards to be fulfilled by the laboratory. During operation of this BSL-3 laboratory at EPHI, the disinfection after each use of the interior working surfaces of the BSCs would generate waste products. All wastes generated in the laboratory (including sample packaging materials, culture materials, Petri dishes, PPE and associated process wastes) would leave the laboratory only after decontamination using the lab's autoclave or after being chemically sterilized. The autoclaving process involves placing waste to be autoclaved in a special container. When autoclaving occurs, an indicator strip on the container changes colour. This allows lab workers and waste management workers to be able to tell at a glance whether waste has undergone autoclaving. Performance of the autoclave is automatically tracked electronically to insure its effectiveness. This method is the same waste management method used by hospitals and similar facilities to sterilize their waste. EPHI will send sterilized wastes produced by the laboratory to incinerator (s) to be installed onsite (within EPHI compound) for waste disposal. The incinerator (s) to be installed at EPHI campus need to fulfil the emission standard on WBG EHS guidelines (2007) see annex 7 the specification for the incinerator.

Table 4: Air Emission Levels for Hospital Waste Incineration Facilities

Pollutants	Units	Guidance value
Total Particulate Matter (PM)	mg/Nm ³	10
Total organic carbon (TOC)	mg/Nm ³	10
Hydrogen chloride (HCl)	mg/Nm ³	10
Hydrogen fluoride (HF)	mg/Nm ³	1
Sulfur dioxide (SO ₂)	mg/Nm ³	50
Carbon monoxide (CO)	mg/Nm ³	50
NO _x	mg/Nm ³	200-400 (a)
Mercury (Hg)	mg/Nm ³	0.05
Cadmium + Thallium (Cd + Tl)	mg/Nm ³	0.05
Sb, As, Pb, Cr, Co, Cu, Mn, Ni and V	mg/Nm ³	0.5

Polychlorinated dibenzodioxin and dibenzofuran (PCDD/F)	Ng/Nm ³ TEQ	0.1
Notes: a. 200 mg/m ³ for new plants or for existing incinerators with a normal capacity exceeding 6 tones per hour, 400 mg/m ³ for existing incinerators with a nominal capacity of 6 tones per hour or less b. Oxygen level for incinerators is 7 percent		

Source: WBG EHS, Health Care Facilities, 2007

These emission levels would be achieved without dilution, at least 95 percent of the time that the plant or unit is operating, to make calculation as a proportion of annual operating hours. Hence, EHPI will plan procurement of incinerators which fulfil this emission standard.

2.6.1 Waste management at proposed BSL-3 RNL Complex Building

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 effective management of healthcare waste is an integral part of a national health-care system, and as such needs to be integrated in this project. Healthcare waste refers to the entirety of waste generated by health care and medical research facilities and laboratories. Though only 10-25% of medical waste is considered hazardous, posing various health and environmental risks, it is essential that a comprehensive plan needs to be developed to prevent and mitigate these risks (WHO, 2004). 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. Segregation of HCW would be done according to the following categories; infectious or clinical waste (hazardous waste), non-infectious or general waste, highly infectious waste, and sharps.

This section focuses on the acceptable waste management practices for BSL 3 laboratory based on the standards recommended by the WHO guideline for Safe management of wastes from healthcare, CDC BMBL, WBG EHS Guidelines and Ethiopian Healthcare waste management guideline and are discussed in this chapter for implementing in the proposed BSL 3 Laboratory.

2.6.2 Type of Waste Expected from proposed BSL 3 NRL Complex

During operation of the BSL-3 laboratories, all wastes generated in the laboratories of the facility (including sample packaging materials, culture materials, petri dishes, PPE, and associated process wastes) would leave the laboratories only after decontamination using the facility's autoclave or after being chemically sterilized. The Ethiopia Healthcare Waste Management National Guideline 2008 categorises HCW into nine classes [(Non Hazardous Waste (Class 1), Clinical Waste (Class 2), Sharps (Class 3), Pathological and Anatomical Wastes (Class 4), Hazardous pharmaceutical and cytotoxic waste (Class 5), Highly Infectious Wastes (Class 6), Radioactive Wastes (Class 7), Waste with high contents of heavy metals (Class 8), and Effluents (Class 9)], Please refer to Annex 10 for further information on the nine categories of HCW for instance; sharps will be put into a separate container (sharp boxes) from other hazardous wastes as well as non-hazardous wastes.

Currently, EPHI laboratories provide several laboratory services for community and public health management including referral laboratory services for whole country. The EPHI laboratories are Microbiology laboratories, TB culture and molecular laboratory, Hematology laboratory, clinical chemistry laboratory, HIV molecular laboratory, Parasitology, Virology (Polio, measles & influenza) laboratories, food microbiology laboratory, Vaccine production and diagnostic laboratory, Environmental and zoonosis laboratories. These laboratories have been providing services for diseases diagnosis, monitoring of treatment outcomes, early detection of epidemic diseases and generating data for researchers. It is well known that during the operation of these laboratories, solid and liquid waste including hazardous and non-hazardous waste are produced and most of the laboratories produce infectious waste and the waste that generated from the existing EPHI laboratories are summarized below in table 5.

Table 5: Waste generated from the existing EPHI laboratories with estimated average quantity, type and source

Type of waste	Waste description	Source facility/laboratory	quantity of waste generated per day	Treatment Method
Infectious waste	Items contaminated with blood and body fluids, including cotton, infected blood, patient samples and specimens, Cultures; stocks and microorganisms; dishes and devices used for culture	Microbiology laboratories, TB culture and molecular laboratory, Hematology laboratory, clinical chemistry laboratory, HIV molecular laboratory, Parasitology, Virology (Polio, measles & influenza) laboratories, food microbiology laboratory, Vaccine production and diagnostic laboratory, Environmental and zoonosis laboratories including mobile BSL 3 lab	104 kg	Infectious wastes are disinfected / sterilized using autoclave at the laboratory; finally incinerated in high temperature in EPHI compound.
Pathological waste	Human tissues, fluids; body parts; unused blood products.	Microbiology laboratories, TB culture and molecular laboratory, Hematology laboratory, clinical chemistry laboratory, HIV molecular laboratory, Virology (Polio, measles & influenza) laboratories, Vaccine production and diagnostic laboratory, and zoonosis laboratories.	8 kg	Chemical disinfection,/ sterilized using autoclave at the laboratory; finally incinerated in high temperature in EPHI compound.
Sharps	Needles; syringes; scalpels; blades; glass, etc.	Microbiology laboratories, TB culture and molecular laboratory, Hematology laboratory, clinical chemistry laboratory, HIV molecular laboratory, Parasitology, Virology (Polio, measles & influenza) laboratories, food microbiology laboratory, Vaccine production and diagnostic laboratory, Environmental and zoonosis laboratories, specimen collection section.	9 kg	All used sharps will be placed in specific cardboard boxes, and incinerated in an appropriate double-chamber (>850°C) incinerator in EPHI compound.
Liquid Waste	Waste generated in the laboratories (biological and chemical liquid waste)	Microbiology laboratories, TB culture and molecular laboratory, Hematology laboratory, clinical chemistry laboratory, HIV molecular laboratory, Parasitology, Virology (Polio, measles & influenza) laboratories, food microbiology laboratory, Vaccine production and diagnostic laboratory, Environmental and zoonosis laboratories.	360 litres	All effluents are disinfected with bleach and drained to a septic tank or cesspool for both storage and treatment in the compound of EPHI.
	Sanitary liquid waste		1640 litres	Sanitary liquid waste are drained to a septic tank or cesspool for both storage and treatment in the compound of EPHI.
Non-hazardous Waste	paper, cardboard and other non-contaminated materials	Generated from all EPHI laboratories and facilities	60 kg	Non-hazardous wastes are incinerated after sorting.

Regarding proposed BSL 3 NRL complex, clinical waste (class 4), sharps (class 3) highly infectious wastes (class 6), chemical wastes (class 8), and Effluents (Class 9) are expected to be the most generated waste from the EPHI BSL 3 Laboratory complex and the following waste are the list of wastes generated from the operation of the laboratory:

- I. Waste cultures and stocks of microorganisms or etiologic agents (class 6):**
 - Cultures and stocks of infectious agents or microorganisms
 - Cultures of specimens from medical and pathological laboratories.
 - Disposable containers, materials, and supplies that may have been contaminated during the manipulation of microbial cultures and stocks
 - Wastes from the production of biological (including all tissue culture materials).
- II. Human pathological wastes including human blood, blood products and their containers Waste (class 4 and 6),**
 - Pathological waste consists of human tissues; organs; body parts; dialysate; cerebrospinal, synovial, pleural, peritoneal, and pericardial fluids; and their respective containers.
 - Human blood and blood products waste (e.g. blood plasma, platelets, red or white corpuscles, and other derived licensed products such as interferon, etc.)
 - Items saturated or dripping with human blood or blood products.
 - Items caked with dried human blood or blood products.
- III. Used sharps waste (class 3),**
 - This category includes used hypodermic needles, syringes (with or without the attached needles), glass Pasteur pipettes, scalpel blades, blood vials, test tubes, needles with attached tubing,
 - Broken plastic culture dishes, unbroken glass culture dishes, and other types of broken and unbroken glassware that was in contact with infectious material including microscope slides and covers lips.
- IV. Chemical waste (class 8),**
 - Chemicals used in the production of biological, laboratory reagents; film developer; disinfectants (such as formaldehyde, chloroform, phenol, ethyl alcohol, isopropyl alcohol, amyl alcohol, and sodium hypochlorite) that are expired or no longer needed; solvents; outdated, contaminated and discarded chemicals
- V. Non-hazardous waste (class 1),**

- Although the generation of the non-hazardous waste almost negligible from BSL 3 laboratory, there may be paper, cardboard and other non-contaminated materials from BSL 2 laboratories, PTPC, Biobank, central warehouse and LEMC.

VI. Liquid Waste (class 9),

- Biological and chemical liquid waste generated in the laboratories

2.6.3 Quantities of Waste Expected from proposed BSL 3 NRL Complex and Current practices

The EPHI laboratories such as Microbiology laboratories, TB culture and molecular laboratory, HIV molecular laboratory, Parasitology, Hematology laboratory, clinical chemistry laboratory, Virology (Polio, measles & influenza) laboratories, food microbiology laboratory, Vaccine production and diagnostic laboratory, Environmental and zoonosis laboratories have been providing services for diseases diagnosis, monitoring of treatment outcomes, early detection of epidemic diseases and generating data for researchers. These laboratories are expected to generate solid and liquid waste including hazardous and non-hazardous waste, and most of the laboratories produce infectious waste with different type and quantity of waste (summarized in table 5 above). The waste are managed according to waste management procedures.

An assessment of was conducted to the estimate volume and type of waste generated from all EPHI laboratories in October 2017. An observational checklist adopted from the WHO healthcare waste management inventory tools was used to assess and capture data on waste management at different departments of the EPHI laboratories. Besides, a questionnaire was used to obtain information on how the laboratory dispose of and manage healthcare wastes in each of the department. Data on volume and type of waste were collected for two weeks on daily basis and each solid waste generated from each laboratory was measured using balance and recorded for two weeks and liquid waste volume also are measured. Finally, we calculated an average volume and type of waste generated from EPHI laboratories.

According to the assessment conducted to assess the estimation of health care waste the finding showed that the estimated the volume of waste being generated on average around 120kg (600 kg per week) hazardous/infectious solid waste per day in addition, an average non-hazardous waste was estimated to be 60kg per day (300 kg per week). Regarding liquid waste, about 2000 litres (10, 000 litres per week) of liquid wastes were generated from laboratory and sanitary and toilet.

Of 2000 litres liquid waste, the laboratories generated an average of 360 litres hazardous liquid waste per day. In addition, we tried to assess the waste of the mobile BSL 3 laboratory found at EPHI and the finding showed that the minimum waste generated was about 2.5 kg and a maximum of 5 kg per day with an average 4 kg, (8 kg per week) regarding laboratory liquid waste a minimum of about 35 litres liquid waste per day and a maximum of 85 litres liquid waste per day with an average 60 litres (300 litres per week) and the sanitary liquid waste a minimum of about 150 litres liquid waste per day and a maximum of 200 litres liquid waste per day with an average 175 litres (3,500 litres per week). Although non-hazardous waste from BSL 3 laboratory is rare due to handling of highly infectious, it was estimated to be about 1 kg (2 kg per week).

However, the proposed BSL 3 laboratory will perform five times more activities than the Mobile BSL 3 Laboratory so that the proposed BSL 3 laboratory would be expected to generate more solid and liquid wastes. Therefore, the proposed BSL 3 laboratory will be expected to generate about 20 kg of solid wastes (gloves, pipette tips, culture tubes, tissues, and other wastes) per day and an average 100 kg per week. Other non-hazardous solid waste would be estimated to be about 5 kg per day with 15 kg per week. Moreover, sanitary liquid waste also would be generated from the proposed BSL-3 facility. Sanitary waste would be generated from such activities and from toilets, showers, and sinks in the building bathroom facilities. As the mobile BSL 3 laboratory generated 15 litres laboratory liquid waste per day and a maximum of 35 litres liquid waste per day with an average 25 litres (125 litres per week) and about 120 sanitary liquid waste per day (600 litres per week). The proposed BSL 3 laboratory would be use five time than the mobile BSL 3 laboratory so that laboratory liquid waste would be 125 litres liquid waste per day (625 litres per week) and sanitary liquid waste generated will be about 360 litres per day (1800 litres per week) can be produced by toilets and showers.

Regarding to other units in the BSL 3 lab complex, Since the PTPC and Biobank (negligible quantities of hazardous waste expected from Central warehouse and LEMC) have very limited activities to generate waste so that infectious/hazardous solid waste from the proposed PTPC and Biobank would be about 5 kg per week. However, BSL 2 labs would perform several activities, and about 20% activities of the existing BSL 2 laboratories will perform so the estimated hazardous solid in the BSL labs would be 20 kg per day with about 80 litres of liquid waste. The liquid waste from PTPC and Biobank would be 75 liters liquid waste per day (375 litres per week) and sanitary

liquid waste generated from BSL 2, PTPC, Biobank, LEMC and Central ware would be about 300 litres per day (1500 litres per week) can be produced by toilets and showers. Regarding non-hazardous waste from BSL 3 laboratory complex building, although the majority of the non-hazardous waste is expected from BSL 2, PTPC, Biobank, LEMC and Central would be estimated about 20 kg per day (100 kg per week). In addition, about 60 liters liquid waste would be estimated to be generated during the NRL BSL 3 complex offices, corridors and other utilities cleaning. The summary of type of waste, quantities to be generated from the BSL 3 NRL complex and treatment methods are described in Table 6.

Regarding hazardous chemicals, all hazardous chemicals used in the proposed BSL 3 laboratory complex building (such as formaldehyde, chloroform, phenol, ethyl alcohol, isopropyl alcohol, amyl alcohol, and sodium hypochlorite) would not become waste for this facility. Only small quantities of these chemicals are enough for daily activities would be present in the facility at any time. However, from the BSL 3 NRL complex (BSL 3 NRL, BSL 2 Labs, PTPC, Biobank center, Central ware house & LEMC) about 3 liters would be expected. These chemicals would either be used up in process that becoming non-hazardous or would leave the laboratory as a stabilizing or sterilizing chemical for samples/waste being sent out. Liquid chemical waste generation may need pH adjustment prior to discharge to the sanitary sewer system if it is too alkaline to meet discharge standards.

2.6.4 Waste management within BSL 3 NLR Complex Building

All biological wastes from BSL-3 and BSL 2 laboratories, PTPC are decontaminated and marked as “treated biohazard waste” prior to disposal in designated containers for treated infectious waste. Decontamination and disposal are the responsibility of the person/laboratory generating the waste. EPHI has waste disposal locations, pickup procedures, safety manual for waste management and BSL-3 mobile laboratory waste management procedure. The proposed BSL-3 laboratory will have procedures for compliance with all applicable regulations for collecting, storing, processing, and disposing of sanitary liquid wastes, solid wastes and hazardous wastes generated from BSL-3 lab at EPHI.

All biological waste from the BSL-3 laboratory would undergo either autoclaving or chemical disinfection. These wastes would be discharged from laboratory sinks, floor drains, or the tissue digesters and would be held and disinfected in retention tanks before being discharged into the

sanitary sewer system. Tap water entering the BSL-3 laboratories through spigots in the sinks or shower heads would have backflow preventers to protect the potable water distribution system from contamination. Biological cultures could be disposed off in the sinks after undergoing treatment with chemical disinfectants for an appropriate amount of time. The autoclaving process involves placing waste to be autoclaved in a special container. When autoclaving occurs, an indicator strip on the container changes its colour. This allows facility workers and waste management workers to be able to tell at a glance whether waste has undergone autoclaving. To manage the waste generated from the proposed BSL 3 laboratory the following mitigation strategies will be implemented.

2.6.5 Waste Minimization

The best practice is to ensure that all laboratory section minimize their waste generation to the barest possible minimum. Appropriate plans, strategies and actions would be established to ensure adequate HCW minimization at source. Accordingly, EPHI BSL 3 laboratory will implement the following waste minimization strategies

- Make Purchasing restrictions to ensure the selection of less wasteful materials;
- Recycle materials and products if applicable
- Ensure good management and control practices especially in the purchase and use of pharmaceuticals; and
- Enforcing a rigorous and careful segregation of the HCW at source.

2.6.6 Waste Segregation

Proper segregation of waste at source generation (at each laboratory section/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. Waste segregation and waste colour coding work hand in hand. The waste generated from BSL 3 laboratory complex, described above, will be segregated and color-coded as outlined below in Table 6 as recommended by WHO.

Table 6: BSL 3 laboratory waste collection and segregation methods

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.
Chemical waste	Brown, labelled with appropriate hazard symbol.	Plastic bag or rigid container.	On demand.
Non- hazardous Waste	Black	Plastic bag inside a container or container which is disinfected after use.	When three-quarters filled or at least once a day.

2.6.7 Colour Coding

Color coding is done by using colors 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. Color 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 color 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. The recommended colour codes for health facilities are shown in Tables 7. 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, it 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 will 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.

Table 7: Three-bin system used at all health faculties in Ethiopia

Segregation category	Color Coding	Container	Examples
Non-risk/ non-hazardous waste	Black	Bag or bin	paper, ash, cardboard
Infectious clinical waste (different type)	Yellow	Bag or bin	Laboratory waste, materials potentially infected blood, swabs Cultures of TB laboratories, contaminated blood clots and glassware
Sharp waste	Yellow	Bag or bin	Syringes with needles, blades
Effluents	Red	Flask or container	Waste water

2.6.8 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.

2.6.9 Labelling

An important aspect of colour coding is labelling. All waste bags or containers would be labelled with basic information in Amharic language and or in English. Basic label information would include type of waste in the container; name of the laboratory section, date of collection and, warning of hazardous nature.

- 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 Medical Departments gather data on the amount of waste produced in each department.

2.6.10 Collection of Waste from BSL 3 NRL Complex

Collection of waste is extremely important particularly to avoid over spilling of waste out of collection containers. Collection would 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 would be done by approved and trained personnel fully equipped with appropriate PPEs and conveying machinery such as laboratory trolley and carts. BSL 3 laboratory staff will 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 as per Guidelines for Management of each Class of HCW as shown in Annex 10.

The following would also be adhered to when collecting waste

- All HCW would be sorted on site before collection and transportation. This will bring about easy identification of content of containers thus preventing careless handling and the risk of secondary infection.
- There would be a fixed schedule for the collection of waste bags and containers from each medical department. This is to ensure the regular removal of waste from each location and to ensure coordination between medical staff and cleaning or housekeeping staff. The minimum frequency of waste removal would be once per working shift.
- No bags would be removed without labelling indicating the point of generation (department, office and laboratory section) and content;

- Laboratory workers would immediately replace the bags or containers with new ones of the same type.
- There would be separate schedules and separate collection times for different colour coded containers. Separate trolleys would be used for different types of waste.
- Vehicles will be disinfected and cleaned daily or at the end of haulage with an appropriate disinfectant at an appropriate site where wastewater will be properly disposed of.
- Waste ducts that convey sacks of waste by gravity will not be used, as they tend to scatter wastes at the exits of the chutes, and are subject to fouling by the wastes, leading to nuisances such as smell and insects.
- Carts and vehicles used to transport the waste will be carefully designed so that they are stable, quiet in operation, and so that transportation can be achieved with the minimum of effort and inconvenience.
- Trolleys or carts would be large enough so that waste is not piled up on them in an unsafe way and the trolleys and carts would be designed to prevent and accommodate any form of spillages.
- Waste bags would not be hand carried around the HCF, since it increases the risk of injury to the legs, arms and torso from incorrectly disposed of sharps or other items.
- Sealed sharps containers would be placed in a labelled, yellow infectious health-care waste bag before removal from the healthcare or laboratories.
- Water and hand-wash materials would be readily available for healthcare waste handlers to wash their hands after handling HCW.

2.6.11 Handling Waste at BSL 3 NRL Complex

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

- **Sharps:**
 - When handling sharps, needles will not be recapped or bent.
 - Syringe will be placed in a safety box immediately.

When there is a need to use needle removers, it will take place immediately after the injection. Safety boxes will be fully and properly assembled before use.

- Safety boxes will also be sealed and collected when they are $\frac{3}{4}$ full and will never be emptied or opened.
- Sharps containers (i.e., safety boxes) will be placed as close to the point of use as possible and practical, ideally within arm's reach.
- Safety boxes will be labeled so that people will not unknowingly use them as a garbage container for discarding other items.
- Safety box will not be shaken to settle their contents.
- Safety boxes will not be placed in high traffic areas (corridors outside laboratory rooms or sample preparation rooms) where people could bump into them or be stuck by someone carrying sharps to be disposed of.
- Containers will not be placed on the floor or anywhere they could be knocked over.
- **Infectious waste bins:**

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

2.6.12 Waste Handling Safety Measures at BSL 3 NRL Complex

1. All personnel handling infectious medical waste will wear gloves and additional protective medical clothing and personal protective equipment (PPE) appropriate to the level of risk they encounter and will remove any protective medical clothing used prior to leaving the work area and to place it in a designated area or container. List of PPE is described in this chapter. When performing procedures where splashing is not expected, gloves are the minimum PPE that would be worn;
2. Protective medical clothing and PPE would not be submitted for laundering unless sterilized;
3. When performing procedures where splashing may occur or when infectious medical waste bags or containers may contact more than the worker's hands and wrists, the following medical protective clothing and PPE is provided in addition to gloves;
 - Appropriate protective medical clothing would be of material that does not permit infectious medical waste from penetrating and reaching workers clothes or skin;
 - Eye protection, surgical face masks, and face shields when personnel may

reasonably anticipate facial exposure to infectious medical waste. Additionally, immunization will be undertaken for staff members, as necessary (e.g. vaccination for hepatitis B virus, tetanus immunization).

2.6.13 Waste Storage at BSL 3 NRL Complex

Storage is classified into internal and external. Consideration for storage will 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 will 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 to avoid cross-contamination.

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 3 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. There 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 be on a daily basis. 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. External storage location would be isolated at EPHI compound where larger containers found near to incinerators would be used to store waste until it is incinerated.

To ensure that waste is kept separated, the central storage receptacles for each colour coded bag will be placed in similarly colour coded receptacles.

- There will be one or more external storage points for hazardous and non-hazardous waste depending on the layout of BSL 3 laboratory.
- The external storage point(s) for the hazardous and non-hazardous waste will be geographically separate at BSL 3 laboratory section.

- The walls and floors would be smooth, without cracks, impervious, easy to clean and disinfect
- The site will be spacious, well ventilated and lit;
- All loading and unloading of waste would take place within the designated collection area around the storage point;
- Larger volume waste bins would be available at the external storage facility to receive waste containers from the internal storage points.

BSL 3 laboratory at EPHI will designate an area within its premises where waste may be temporarily stored until final collection for disposal and onward treatment. It is expected that BSL 3 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 and it would be included in design of the proposed BSL 3 building. In addition waste storage area will be large enough to contain all the hazardous waste produced by the institute with space capacity to cope with any maintenance or breakdown of the treatment unit. The storage area would be totally enclosed and secured from unauthorized access, inaccessible to animals, insects, and birds, and easy to clean and disinfect with an impermeable hard-standing base, good water supply, drainage, and ventilation.

2.6.14 Waste Transportation

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 3 NRL complex is treated at EPHI facility, off-site transport will be done for fly and bottom ash, sludge and wastewater (if it required).

2.6.14.1 On site transportation

The 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* and 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, trolley, or containers used for the transportation of health-care waste would not be used for the transportation of any other material; and would be used for transporting safety boxes and bins
- Waste that has the potential to leak will 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 will be used for transporting safety boxes and bins.
- The collected waste will not be left even temporarily anywhere other than at the designated storage room.
- Containers would be covered with lids during storage and transport.

2.6.14.2 Off-site Transportation

During the transportation of waste outside the EPHI compound the following safety precautions would be included: -

- Single-bagged waste and containers of sharps and liquids would be placed within a rigid or semi-rigid container such as a bucket, box, or carton lined with a plastic bag.
- Containers would be covered with lids during transportation.
- When transporting plastic bags of infectious waste, care would be taken to prevent tearing of the bags.
- Infectious waste would not be compacted before treatment.
- Outside EPHI, infectious waste would be transported in closed, leak-proof, rigid containers using trucks
- The transportation would be properly documented, and all vehicles will carry a consignment note from the point-of collection to the treatment facility.
- Vehicles used for the carriage of waste would be disinfected prior to use for any other purpose.
- The vehicles would be free of sharp edges, easy to load and unload by hand, easy to clean and disinfect, and fully enclosed to prevent any spillage in the facility premises or on the road during transportation.
- The vehicles would carry adequate supplies of plastic bags, protective clothing, cleaning tools, and disinfectants to clean and disinfect in case of any spillage.

- Staff would be properly trained in the handling, loading and unloading, transportation, and disposal of waste
- Staff would be fully aware of emergency procedures for dealing with accidents and spillage.

2.6.15 Waste Treatment and Disposal Methods for BSL 3 NRL Complex

The World Health Organization (WHO) recommends that waste treatment techniques which minimize the formation and release of chemicals or hazardous emissions would be given priority. In general, proper treatment and disposal of healthcare waste is necessary to ensure that its impact on the environment and human health is minimized or eliminated. Among all the current existing technologies for the treatment and disposal of HCW, the most appropriate technology will be applied, and this would be the most reliable, affordable, and sustainable technology in accordance with the technical, human and financial resources of BSL 3 laboratory. Moreover, the technology would also minimize the immediate public health risks associated with HCWM with the lowest impact on the environment. So that several methods are appropriate for infectious waste treatment, depending on the type of waste material. These treatment methods will include one of the following options or combination of options: steam sterilization, incineration, thermal inactivation, gas/vapor sterilization, chemical disinfection, and sterilization by radiation, or electromagnetic radiation. The treatment methods for waste generated from BSL 3 laboratory are described in table 8 below

Table 8; Type and quantities of waste expected to be generated from BSL3 NRL Complex and Treatment methods

Waste category	Type of waste	Source Facility/Laboratory	quantity of waste generated per day	Treatment Method
Waste cultures and stocks of microorganisms or etiologic agents	Cultures and stocks of infectious agents or microorganisms Cultures of specimens from medical and pathological laboratories Disposable containers, materials, and supplies that may have been contaminated during the manipulation of microbial cultures and stocks	BSL 3 NRL, BSL 2 Labs, PPTC & Biobank centre	33.5 kg/day	Infectious wastes are disinfected / sterilized at the laboratory and incinerated in high temperature, double chambered pyrolytic incinerator
Human pathological wastes including human blood and blood products and their containers Waste	Pathological waste consists of human tissues; organs; body parts; dialysate; cerebrospinal, synovial, pleural, peritoneal, and pericardial fluids; and their respective containers Human blood and blood product wastes (e.g. blood plasma, platelets, red or white corpuscles, and other derived licensed products such as interferon, etc.) Items saturated or dripping with human blood or blood products Items caked with dried human blood or blood products--	BSL 3 NRL, BSL 2 Labs, PPTC & Biobank centre	6.5 kg/day	Chemical disinfection, Wet thermal treatment/ autoclave and Incineration (Pyrolytic incinerator) Highly infectious waste, such as cultures from lab work, should be sterilized using autoclave. Pathological waste should be treated using Incineration (pyrolytic incinerator).
Used sharps waste	This category includes used hypodermic needles, syringes (with or without the attached needles), Pasteur pipettes, disposable plastic pipettes, scalpel blades, blood vials, test tubes, needles with attached tubing, Broken plastic culture dishes, unbroken glass culture dishes, and other types of broken and unbroken glassware that was in contact with infectious material including microscope slides and covers lips.	BSL 3 NRL, BSL 2 Labs, PPTC & Biobank centre	5 kg/day	All used sharps will be placed in specific cardboard boxes called safety boxes and incinerated preferably in an appropriate double-chamber (>850°C) incinerator, in EPHI compound.

Chemical waste	laboratory reagents; disinfectants (such as formaldehyde, chloroform, phenol, ethyl alcohol, isopropyl alcohol, amyl alcohol, and sodium hypochlorite) that are expired or no longer needed; and contaminated chemicals	BSL 3 NRL, BSL 2 Labs, PPTC, Biobank centre, Central ware house & LEMC	3 liter/day	Diluting with a distilled water and/ or neutralization using a lime or acid. Return expired drugs to supplier;
Liquid Waste	Biological and chemical liquid waste generated from BSL 3 Labs and BSL 2, PTPC, Biobank centre	BSL 3 NRL, BSL 2 Labs, PPTC & Biobank centre,	280 litres/day	All effluents will be disinfected with bleach and drained to EPHI's liquid waste treatment plan or cesspool for both storage and treatment in the compound of EPHI.
	Sanitor liquid waste from BSL 3 NRL complex	BSL 3 NRL, BSL 2 Labs, PPTC, Biobank centre, Central ware house & LEMC	720 litres/day	Sanitary liquid wastes are drained to a septic tank or cesspool for both storage and treatment in the compound of EPHI.
Non-hazardous wastes	Paper, cardboard and other non-contaminated materials.	BSL 3 NRL, BSL 2 Labs, PPTC, Biobank centre, Central ware house & LEMC	23 kg/day	Non-hazardous wastes would be incinerated after sorting.

2.6.16 BSL 3 NRL complex waste incineration technology

As the existing incinerators do not fulfil the emission requirements of the World Bank EHS guideline, they will be removed from site following manufacturer's recommendations and procedures. Hence, the following options were considered. First, transportation of the decontaminated waste from the BSL3 lab wastes to an existing national centralized waste facility located 90 Km away from Addis Ababa. Nevertheless, this option is risky and expensive in the context of Ethiopia. The second option is on-site treatment using pyrolysis incinerator with a capacity to burn 50 kg per hour with emission reduction device control (Fabric filter coated with catalyst) made from PTFE, with parallel dedusting, lower contamination of filter dusts because of PCDD/PCDF destruction at the catalytic surface that have high efficiency reduction of dioxin up to <0.1 ng TEQ/m³. The second option is the preferred option at this stage. However, since this project will finance the design (and feasibility study) of the BSL3 lab during project implementation, the current ESIA will be updated (together with the relevant ESMP) before works are contracted (or commence) (See annex 7 for specification). EHPI will be responsible to hire a competent and experienced organization/firm which can handle demolition of the existing incinerators before the BSL3 lab becomes operational.

EPHI will also be responsible for allocation of the necessary resource for mitigation of environmental and social risks associated with the demolition of the existing incinerators as well as for compliance monitoring and reporting. The demolition process will also be monitored by Environment, Forest and Climate Change Authority of Addis Ababa, which is a regulatory organ in environmental safeguards issues. The detail implementation arrangement for demolition and disposal of the exiting incinerators is outlined in the ESMP (Table 17). This ESIA will be updated to cover risks associated with the demolition/decommissioning. Agreement will be signed with the supplier of the new incinerator so that it could train the incinerator operators, conduct periodic maintenance and supply spare parts when needed.

2.6.17 Waste Disposal Methods for BSL 3 NRL complex

Disposal of hazardous ash: Fly ash and bottom ash from incineration is generally considered to be hazardous, because of the waste would have a heavy metal content and dioxins and furans. The waste will be collected and then solidified with cement/ encapsulated in double containers made

from polyethylene material to transport in safe manner to disposal site utilized by Kotebe waste treatment plants for landfilling. Alternatively, the homogeneous mixture would be transported in liquid state to Kality wastewater treatment plant and then the treated sludge will be disposed in secured manner at landfilling disposal site utilized by Addis Ababa water and sewerage Authority. As plan B, Sendafa Sanitary landfill will be considered for final disposal of handling incineration residues if this would be socially and environmentally feasible. The updating of the ESIA, ESMP and ICWMP during implementation will also consider the assessment of the capacity of Kotebe waste treatment plant and Sendafa sanitary landfill for handling incineration residues.

2.6.18 Liquid Waste Generated from BSL 3 NRL Complex Treatment and Disposal

Liquid contaminated waste (e.g. pathological sample, blood, faeces, urine, other body fluids and contaminated fluid) requires special handling, as it may pose an infectious risk to healthcare workers with contact or handle the 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 3 laboratory and carry it below ground to a central location for treatment at EPHI. The treatment plant is located at a facility, and wastewater collected from laboratory by pipe system and passed into different units of liquid waste treatment units. Liquid wastes generated from the BSL 3 NRL complex, which contains pathogens blood and hazardous chemical, except hazardous chemical they are treated with disinfectants, and finally it is disposed off into liquid waste treatment plant which will be constructed during the construction of BSL 3 laboratory, the proposed liquid waste treatment plan design described below and shown in figure 7. Liquid wastes with highly infectious 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 should be treated before disposal. Although chemical, wastes small quantity, all hazardous chemicals used in this BSL3 lab (such as: formaldehyde, chloroform, phenol, ethyl alcohol, isopropyl alcohol,

amyl alcohol and sodium hypochlorite) would not become waste for this facility. Only small quantities of these chemicals (enough for daily activities) would be present in the lab at any time. These chemicals would either be used up in process (becoming non-hazardous) or would leave the facility as a stabilizing or sterilizing chemical for samples being sent to other laboratories. Waste fluid generated from the BSL3 NRL may need pH adjustment. Effluent from the lab also needs to meet the standard in Table 9 to be discharged into publicly operated sewage collection and treatment systems at Addis Ababa. Regarding sanitary liquid waste, the sanitary waste can be generated from the proposed BSL-3 lab. Sanitary waste could be generated from research activities and from toilets, showers and sinks in the building bathroom facilities; the sanitary liquid waste management described below.

2.6.19 Liquid waste management plan for EPHI's BSL 3 NRL Complex

Waste water from the BSL 3 NRL complex is a health hazard because it could be a potential source of pathogenic microorganisms. Not only that, the laboratory liquid waste can potentially constitute surfactants, detergents, reagents, high organic content waste, disinfectants, general waste from wash rooms of laboratory wastes apparatuses. If released to the environment without proper treatment can perturb the surface water. Other than this, the facility also generates human waste which can be classified as general waste or sanitary waste.

The BSL 3 laboratory will instigate up to the standard liquid waste treatment and management methods. However, since the liquid waste that will be generated is of different type, a tailor-made approach will be used. The first one involves off-site waste treatment and the second involves on-site waste treatment. The offsite-waste treatment will be applied in BSL3 lab of EPHI to dispose human excretory. For this reason, a well-designed manhole will be constructed together with the BSL 3 NRL complex to temporarily hold human wastes from toilets and the waste will be disposed on an offsite dumping and treatment station with the care of an authorized organization. In other words, offsite disposal and waste management of the general waste will be outsourced to a certified organization. The Addis Ababa water and sewerage authority is an authorized organization to collect and manage general or sanitary wastes. The Kaliti waste treatment facility is administered by the authority. As a result, as shown in section 2.6.20 (final disposal of waste water and sludge), the waste will be managed in such a way, the authority will periodically siphon the waste from the manhole and transport it and treat it in the Kaliti waste treatment plant.

On the other hand, the liquid waste which is generated from the laboratory activities will be managed onsite and a designated waste treatment facility will be constructed within the institute, therefore the design of the BSL 3 will consider the establishment of this treatment system as its integral part. The treatment system will be designed in such a way to reduce the level of pollution load which can primarily be defined in terms of BOD, COD, total organic carbon, oil and grease, total coliform etc. the treatment system will majorly encompass physical and disinfection of the liquid waste. The physical treatment involves the application of septic tank treatment setup and the disinfection process involves UV irradiation.

I. Components of the liquid waste management plan

Developing and implementing an effective onsite wastewater management program requires that a systematic approach be used to determine necessary program elements. The following are basic elements of the onsite liquid waste management plan.

2.6.20 Onsite waste treatment for the BSL3 laboratory

The onsite waste treatment system which will be constructed in EPHI will have four stages of treatment, to reduce the level of BOD and microbial load before it is released to surface water or transported to a centralized treatment/disposal facility. The process will entail Septic tanks, sand/media filters, aerobic treatment unit (Aeration-clarifier unit) and ultraviolet irradiation.

1. Septic tanks

The septic tank is the most commonly used wastewater pre-treatment unit for onsite wastewater systems. Tanks may be used alone or in combination with other processes to treat raw wastewater before it is discharged to a subsurface infiltration system. In EPHI's context the tanks will be subordinate with other pathogen removal process. The tank provides primary treatment by creating quiescent conditions inside a covered, watertight rectangular, oval, or cylindrical vessel, which is typically buried. In addition to primary treatment, the septic tank stores and partially digests settled and floating organic solids in sludge and scum layers. This can reduce the sludge and scum volumes by as much as 40 percent, and it conditions the wastewater by hydrolysing organic molecules for subsequent treatment in the soil or by other unit processes (Baumann et al., 1978).

A septic tank removes many of the settleable solids, oils, greases, and floating debris in the raw wastewater, achieving 60 to 80 percent removal (Baumann et al., 1978; Boyer and Rock, 1992;

University of Wisconsin, 1978). The solids removed are stored in sludge and scum layers, where they undergo liquefaction. During liquefaction, the first step in the digestion process, acid-forming bacteria partially digest the solids by hydrolysing the proteins and converting them to volatile fatty acids, most of which are dissolved in the water phase. The nature of liquid waste in a septic tank varies

2. Sand/media filters

Sand filters are essentially aerobic, fixed-film bioreactors used to treat septic tank effluent. Other very important treatment mechanisms that occur in sand filters include physical processes such as straining and sedimentation, which remove suspended solids within the pores of the media, and chemical adsorption of dissolved pollutants (e.g., phosphorus) to media surfaces. The latter phenomenon tends to be finite because adsorption sites become saturated with the adsorbed compound, and it is specific to the medium chosen. Bioslimes from the growth of microorganisms develop as attached films on the sand particle surfaces. The microorganisms in the slimes absorb soluble and colloidal waste materials in the wastewater as it percolates around the sand surfaces. The absorbed materials are incorporated into new cell mass or degraded under aerobic conditions to carbon dioxide and water. Treatment Processes and Systems Most of the biochemical treatment occurs within approximately 6 inches (15 centimetres) of the filter surface. As the wastewater percolates through this active layer, carbonaceous BOD and ammonium-nitrogen are removed. Most of the suspended solids are strained out at the filter surface. The BOD is nearly completely removed if the wastewater retention time in the sand media is sufficiently long for the microorganisms to absorb and react with waste constituents. With depleting carbonaceous BOD in the percolating wastewater, nitrifying microorganisms can thrive deeper in this active surface layer, where nitrification will readily occur.

3. Continuous-flow, suspended growth aerobic system

The aerobic suspended-growth process that maintains a relatively high population of microorganisms (biomass) by recycling settled biomass back to the treatment process. The biomass converts soluble and colloidal biodegradable organic matter and some inorganic compounds into cell mass and metabolic end products. The biomass is separated from the wastewater through settling in a clarifier for recycling or wasting to sludge handling processes. Preliminary treatment to remove settleable solids and floatable materials is usually provided by a septic tank or other

primary treatment device. Most onsite designs can provide significant ammonia oxidation and effective removal of organic matter. The basic system consists of several interrelated components (as shown in figure **a schematic diagram of the liquid waste treatment facility of BSL3 NRL**):

- i. An aeration tank or basin.
- ii. An oxygen source and equipment to disperse atmospheric or pressurized air or oxygen into the aeration tank at a rate enough to always maintain positive dissolved oxygen.
- iii. A means to appropriately mix the aeration basin and ensure suspension of the biomass (usually accomplished by the aeration system).
- iv. A clarifier to separate the biomass from the treated effluent and collect settled biomass for recycling to the aeration basin.

4. Disinfection: Ultraviolet irradiation

The germicidal properties of ultraviolet (UV) irradiation have been recognized for many years. UV is germicidal in the wavelength range of 250 to 270 nm. The radiation penetrates the cell wall of the organism and is absorbed by cellular materials, which either prevents replication or causes the death of the cell. Because the only UV radiation effective in destroying the organism is that which reaches it, the water must be relatively free of turbidity. To make the water less turbid prior to UV radiation, as described above the effluent will be contained in a septic tank followed by fine treatment in sand/ media filters and suspended growth aerobic system.

Table 9: Expected performance of the BSL3 NRL complex liquid waste treatment units

Treatment units	Performance	Performance enhancements
Septic tank	<p>The main function of a septic tank is to act as a primary settlement tank removing some of the BOD and most of the suspended solids from the waste water</p>	<p>Chemicals such as aluminium sulphate and ferric chloride can be used to enhance settlement in these tanks.</p> <p>Aluminium sulphate is used also if there is a high load of heavy metals. However, previous EPHI's effluent monitoring has demonstrated undetectable level of heavy metals. Thus, in the current system the need for the use of aluminium sulphate will depend on the periodic testing of effluent released from the BSL3.</p>
Sand/media filters	<p>Straining and sedimentation, which remove suspended solids within the pores of the media, and chemical adsorption of dissolved pollutants (e.g., phosphorus) to media surfaces.</p> <p>Removal of carbonaceous BOD and ammonium-nitrogen</p> <p>The BOD is nearly completely removed if the wastewater retention time in the sand media is sufficiently long for the microorganisms to absorb and react with waste constituents.</p> <p>Sand filter effluents have provided more than 3 logs of FC removal and more than 4 logs of poliovirus removal. Since this level of pre-treatment results in a very low final FC concentration (<100 CFU/100mL) removals depend more on the influent concentration than inherent removal capability. This is consistent</p>	<p>To enhance the retention and biodegradation of carbonaceous and nitrogen organic content in the liquor additional successive sand/media filters will be used, however this will depend on the initial testing of effluent loading released from the BSL3</p>

	with several large-scale water reuse studies that show that filtered effluent can reach essentially FC-free levels (<1CFU/100mL)	
Continuous-flow, suspended growth aerobic systems	<p>Converts soluble and colloidal biodegradable organic matter and some inorganic compounds into cell mass and metabolic end products</p> <p>If aeration units are well operated can achieve BOD concentrations ranging from 10 to 50 mg/L and TSS concentrations ranging from 15 to 60 mg/L.</p> <p>Nitrification can also be significant in these aeration units during warmer periods. Some nitrogen removal can be achieved by denitrification, which can remove 30 to 40 percent of the total nitrogen (TN) under optimum conditions. Faecal coliform and virus removal have been reported in the range of 1 to 2 logs.</p>	<p>The use of coarse membrane filters in lieu of, or in addition to, the clarifier; and process enhancement through the addition of an inert media area on which biofilms can grow.</p> <p>The addition of surfaces where biota can become attached and grow increases the capacity of the system.</p>
Disinfection: Ultraviolet irradiation	<p>With UV dosage of about 100 mW-s/cm², while higher (but attainable) effluent FC levels require less dosage to filtered effluent (about 48 mW-s/cm²) than is required by aerobic unit effluent (about 60 mW-s/cm²). This can be attributed to TSS, turbidity, and transmittance. Average quartz tube transmittance is about 75 to 80 percent.</p>	<p>Periodic testing of effluent from the clarifier will be carried out to reduce turbidity, TSS before it is subjected to UV irradiation. The turbidity should be maintained below 0.2 NTU.</p>

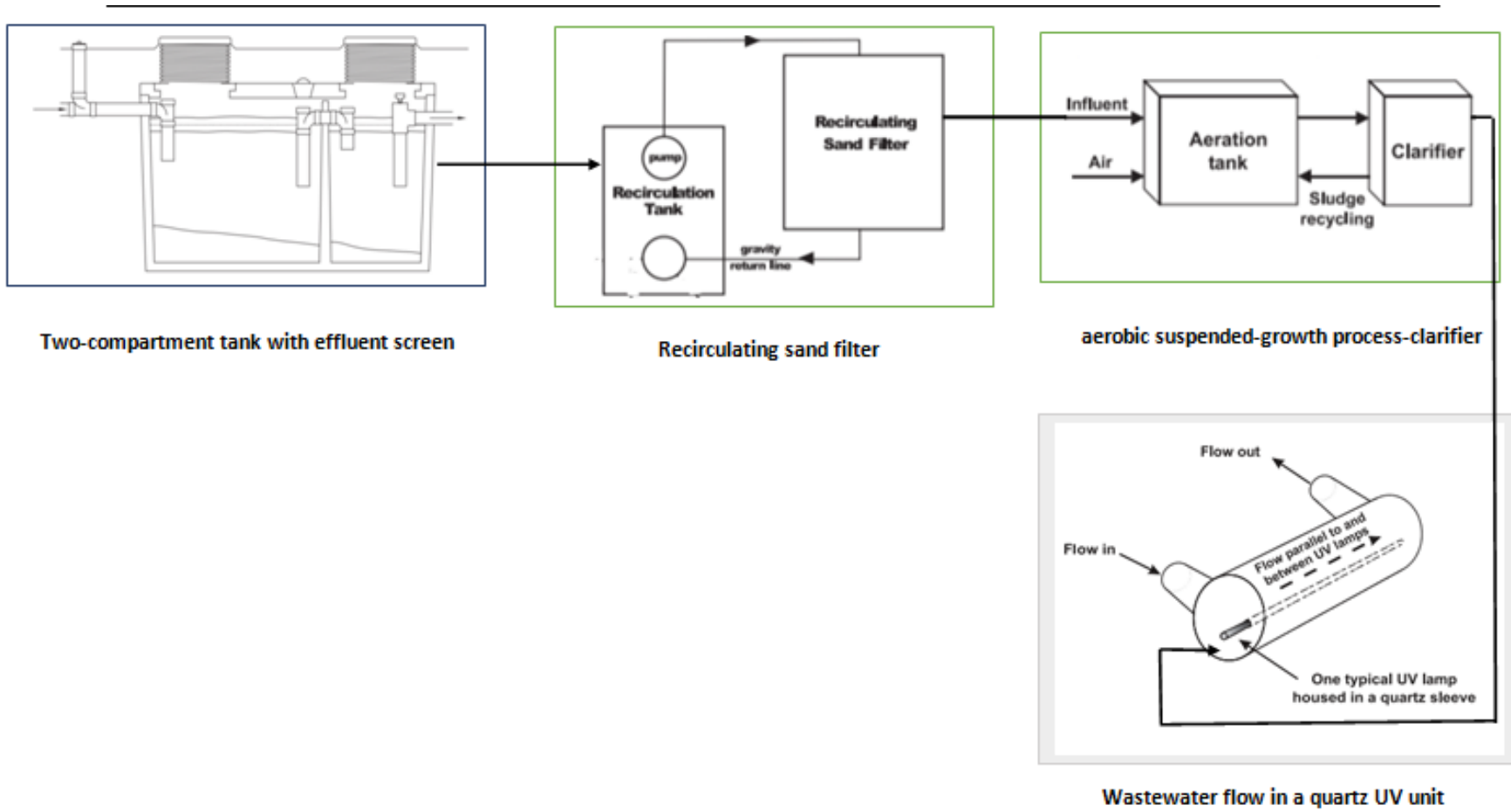


Figure 7: A schematic diagram of the liquid waste treatment facility of BSL3 NRL

2.6.21 Incinerator fly Ash control method

Flue (exhaust) gases from incinerators by burning medical waste can contain fly ash (particulates), heavy metals, dioxins, furans, thermally resistant organic compounds. Currently several convention methods are used to treat incinerator fly ash generated by medical waste incineration. In the future to reduce the impacts raised from the fly ash and flue gases the EPHI will propose to utilize the primary strategies (operation by trained, qualified personnel, use of personal protection equipment, periodic maintenances, Auditing and reporting systems and routine inspection of furnace and air pollution control systems) and secondary strategies like fabric filter coated with catalyst made from PTFE, with parallel “de-dusting” to remove most of the fly ash, lower contamination of filter dusts because of PCDD/ PCDF destruction at the catalytic surface with high efficiency (< 0.1 ng TEQ/m³ with Cement Solidification Technology (CST) and then encapsulated in double containers made from polyethylene material to transport in safe manner to disposal site utilized by Kotebe waste treatment plants for landfilling. Alternatively, the homogeneous mixture can be transported in liquid state to a Kality wastewater treatment plant and then the treated sludge will be disposed in secured manner at landfilling disposal site utilized by Addis Ababa water and sewerage Authority. As plan B, Sendafa Sanitary landfill will be considered for final disposal of handling incineration residues if this would be socially and environmentally feasible. The updating of the ESIA, ESMP and ICWMP during implementation will also consider the assessment of the capacity of Kotebe waste treatment plant and Sendafa sanitary landfill for handling incineration residues.

2.6.22 Final Disposal for Wastewater and sludge

The treated wastewater from EPHI BSL 3 NRL will be released to sewer line of Addis Ababa Water Supply and Sewerage Authority (AAWSSA) Kality treatment plant. However currently the sewer line is under construction and the project will be finalized before our project is commenced for operation (within two years). If the sewer line is not finalized before our project commenced, an alternatively, until sewer line is connected to those treatment plants, the wastewater would be transported to those treatment plants by using sewage trucks that empty septic tanks. Regarding sludge, sludge generated in EPHI would be transported to AAWSSA Kotebe treatment plants that designed to treat and dispose sludge, using vacuum trucks with empty septic tanks. The waste also needs to meet the standard summarized below table to be discharged into publicly operated sewage collection and treatment systems at Addis Ababa.

As it is the case for final disposal of handling incineration residues, Sendafa Sanitary landfill also will be considered for final disposal of wastewater sludge if this would be socially and environmentally feasible. The updating of the ESIA, ESMP and ICWMP during implementation will also consider the assessment of the capacity of Kotebe waste treatment plant and Sendafa sanitary landfill for wastewater sludge.

Table 10: Effluent Levels for Health Care Facilities

Table: Effluent Levels for Health Care Facilities		
Pollutants	Units	Guideline values
pH	S.U	6 – 9
Biochemical Oxygen Demand (BOD5)	mg/L	50
Chemical Oxygen Demand (COD)	mg/L	250
Oil and grease	mg/L	10
Total Suspended Solid (TSS)	mg/L	50
Cadmium (Cd)	mg/L	0.05
Chromium (Cr)	mg/L	0.5
Lead (Pb)	mg/L	0.1
Mercury (Hg)	mg/L	0.01
Chlorine, total residue	mg/L	0.2
Phenol	mg/L	0.5
Total Coliform bacteria	MPN ^a	400
Polychlorinated dibenzodioxin and dibenzofuran (PCDD/F)	Ng/L	0.1
Temperature increase	°C	<3 ^b
Notes: a MPN = Most Probable Number b At the edge of a scientifically established mixing zone which takes into account ambient water quality, receiving water use, potential receptors and assimilative capacity		

These levels should be achieved, without dilution, at least 95 percent of the time that the plant or unit is operating, to make calculations as a proportion of annual operating hours.

2.6.23 Monitoring the liquid waste management system

To maintain the onsite waste treatment operating and maintained sustainable, continuous monitoring system will be established. Both individual systems and sets of systems within a delineated management area would be monitored to ensure proper performance and the achievement of public health and environmental goals. A combination of visual, physical, bacteriological, chemical, and remote monitoring approaches will be used to assess system performance. Specific requirements for

reporting to the appropriate regulatory agency would be also be defined in a management program. The right to enter the institute to access and inspect components of the onsite system is also an essential element of an effective management program.

Effluent guidelines are applicable for direct discharges of treated effluents to surface waters for general use. Guidelines as developed by the World Bank (table 10) will be adopted to compare each end pipe testing. Standards which are expected to be met by the World Bank, will be achieved without dilution, at least 95 percent of the time that the plant or unit is operating, to be calculated as a proportion of annual operating hours. Finally, when the waste water meets the effluent quality standards (summarized in Table 10) it will be connected to sewer lines (being constructed to be finalized before 2 years) or transported to Kality Waste Water Treatment Plant and final disposal of the waste can be accomplished.

2.7 PT and BSL 3 laboratory Sample Handling and Transportation

2.7.1 Sample Transportation and Arrival at the EPHI BSL-3 Facility for Processing

Sample shipments would only be received at the BSL-3 facility operating within the parameters specified in all established guidelines and requirements. If the samples would be select agents, they would only be accepted when the EPHI request form has been completed per regulations, , and the requesting facility responsible official notified in advance of shipment according to WHO requirements. Biological materials or infectious agents could only be shipped to EPHI by commercial package delivery services, the Ethiopian Postal Service, other authorized entity, or delivered to the receiving area from an origination point within EPHI by a designated EPHI employee acting as a courier. All incoming packages (regardless of origination point) containing infectious agents would have to have been packaged fulfil the requirement of the protocol attached as annex 12.

Biological shipments to and from EPHI could initially be as much as ten times the current levels of shipments to existing EPHI biological research laboratories. Once the facility became fully operational and “stocks” of needed materials were established, the level of shipments would remain above current levels for these types of shipments but decrease from start-up levels. Due to the perishable nature of the samples at the BSL-3 facility, receiving and shipping of samples normally would only occur during weekday daylight hours and samples must be opened and used or restored (put in growth media) within 8 hours of arrival. External packaging material from packages received

at the facility would be inspected, removed, autoclaved, and disposed of according to EPHI waste handling procedures. The biological material samples and their packaging would be left intact and in accordance with the established chain of custody record. The packages would be placed in safe and secure condition within the respective

The samples may arrive at EPHI Shipping and Receiving in various fresh, frozen, or “fixed” (for example, in formaldehyde) forms including aqueous liquids, solids, or as material contained in bodily fluids. Samples would normally only contain vegetative forms (active growing stage) of microorganisms, but some spores could be present in samples. Other samples may contain proteins, DNA, or attenuated microorganisms (organisms that have been partially inactivated).

Upon arrival at EPHI Shipping and Receiving, these sample containers would be examined for damage, logged in, and taken to the BSL-3 laboratory for removal of the external packaging material. Damaged packages would be handled in accordance with procedures for BSL-3 laboratories (to be developed once the project obtains approval). The removed packaging would then be autoclaved and disposed as solid waste. The interior packing with the intact sample would be placed safely and securely in the respective BSL-3 laboratory under chain-of-custody procedure until the authorized researcher is ready to process the samples. Unpacking any select agent primary container would only be done in the BSC.

The samples would be stored in the BSL-3 laboratory within a locked freezer or refrigerator, according to the needs of the sample for preservation. Inventories of all samples and cultures would be kept. Samples and cultures would be identified by a numeric or alpha-numeric code rather than by the name of the microorganism or source. Sensitive information about samples and results would be maintained elsewhere at EPHI in a safe and secure manner in accordance with applicable NNSA and EPHI security requirements. The samples could also be immediately processed, in which case the materials would be placed directly into culture media (such as a liquid or semi-solid nutrient material or media). All preparations and manipulations of cultures or samples would only occur within a fully operating BSC. When the external packaging materials were removed, they would be autoclaved within the facility and disposed of according to EPHI’s solid waste handling procedures.

2.7.2 Transport of Samples and PT samples

PT and diagnosis sample shipments would only be received at the laboratory operating within the parameters specified in all established guidelines and requirements. If the PT samples would only be shipped when they have been completed all necessarily process and the receiving facility responsible official notified in when receiving it. Biological materials or infectious agents could only be shipped to laboratories found through the country by commercial package delivery services, the Ethiopia Postal Service, or by EPHI couriers. Generally, shipment sample sizes would be small; a typical sample would consist of about a millilitre of specimen. Smaller samples could be shipped that would be microlitres in size; the maximum probable sample size would be 15 millilitres. The protocol for transporting and handling of samples (such as soil) would be followed during the transportation and handling PT samples by Ethiopia Postal Service, or by EPHI couriers. Receipt of the PT samples would be acknowledged electronically or telephone by the receiving facility responsible official within 36 hours of receipt or paper copy of receipt will be provided to EPHI within 3 business days of receipt.

All shipping containers would be made of plastic and the samples would be double- or triple-contained. Transportation and shipment of biomedical materials and import of select agents would be subject to the requirements of the WHO and IATA for sample transportation. Once the PTPC facility became fully operational and “stocks” of needed materials were established, the level of shipments would be every quarter to 50 facilities and levels for these types of shipments but increase from start-up levels.

Specimens are transported in a containment system

- Primary containment Collection container with screw cap top
- Secondary containment Specimen container in a sealable, biohazard bag
- Place requisition in outside pouch of biohazard bag
- Tertiary containment Specimens in bags are placed in transport box
- Use transport boxes (Styrofoam with fibreboard, plastic, or metal) and ensure lid is securely fastened
- Package 20-30 specimens per box, pack specimens vertically to avoid leaking.
- Use cold chain transport and keep specimens protected from light

In our context due to lack of strong laboratory networking with different levels of Laboratories and regulated sample transport system we use the National postal service for transport of some biological samples from far localities and .therefore it demands to pack specimen containers in triple packing system sealed plastic bags wrapped in bubble wrap and placed in secondary and tertiary biohazard containers, then Put a biohazard label on the outside of the container together with the addressee as detailed by the Postal Regulations for Mailing or according to universal procedure for infectious sample packing and transportation It also requires that any individual transporting an infectious substance be trained in the transportation of infectious substances. Mailing infectious substances by air also falls under the *Dangerous Goods Regulations* (DGR) of the International Air Transport Association (IATA) [www.iata.org]. These regulations set out all the ICAO mandates and the airline industry's universal rules on how to safely package and transport infectious substances.

The following criteria must meet

- Containers should be clearly labeled on the side, not the cap
- Identification number on each specimen container corresponds to the identification number on the specimen log
- Request forms must be separated from specimen container
- Specimen log should include the requested data for each patient
- Do not wrap specimen request or specification forms around containers.
- Number of specimen containers in the box must corresponds to the number of names on the specimen log
- Close plastic bags used for transporting specimens with twist ties or zip-locks.
DO NOT Use Staples, Pins or Needles as they are a common cause of injury when attempting to open bags.
- Date shipped, and the name of the health Centre are included on the specimen log

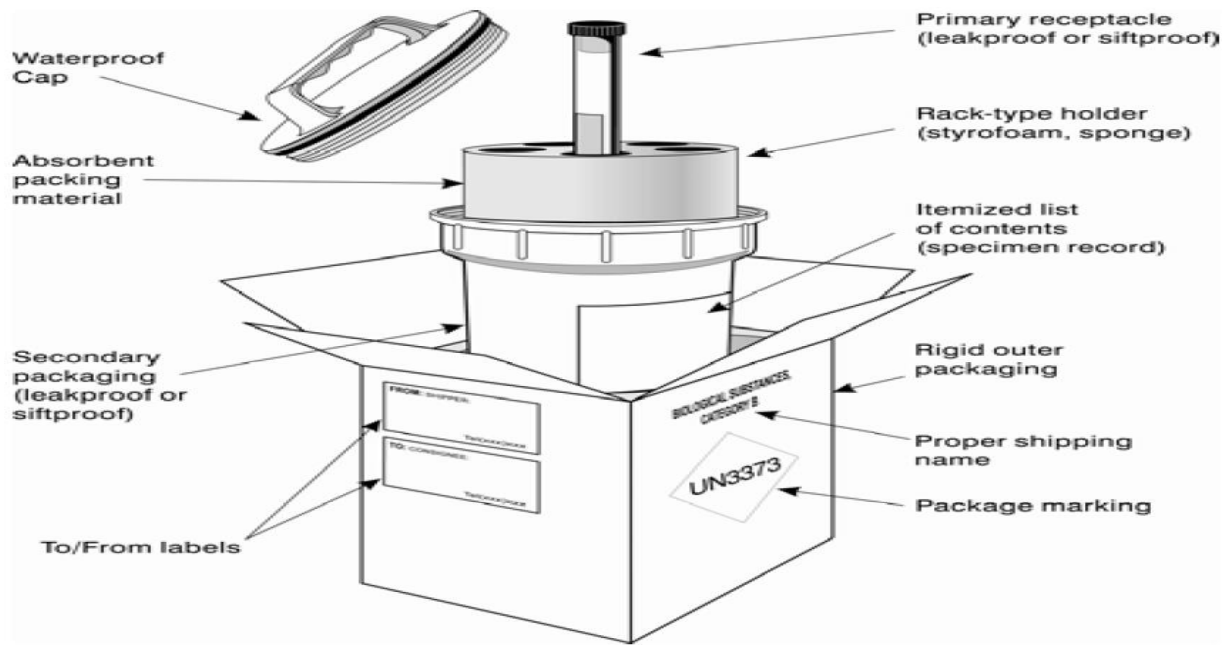


Figure 8: Example of the triple packaging system for the packing and labelling infectious substances (adopted from WHO)

Due to the perishable nature of samples at the PTPC, shipping of samples normally would be done using appropriated temperature (procedure will be developed during the operation phase for each type of specimen) and only occur during weekday daylight hours and samples arrived at facilities must be opened and used or restored (put in growth media) within 8 hours of arrival. External packaging material from packages received at the facility would be inspected, removed, autoclaved, and disposed of according to facility waste handling procedures. The biological material samples and their packaging would be left intact and in accordance with the established chain-of custody record. The packages would be placed in safe and secure condition within the respective laboratory where workers would process them.

Upon arrival at facility receiving, these sample containers would be examined for damage, logged in, and taken to the laboratory for removal of the external packaging material. Damaged packages would be handled in accordance with procedures for laboratories. The removed packaging would then be autoclaved and disposed as solid waste. The interior packing with the intact sample would be placed safely and securely in the respective laboratory under chain-of-custody procedure until the authorized personnel is ready to process the samples. The samples could also be immediately processed, in which

case the materials would be placed directly into culture media (such as a liquid or semi-solid nutrient material or media).

2.8 Quality Assurance for the Proposed BSL 3 Laboratory

As the mission of EPHI is to improve the health of the general public of Ethiopia through undertaking research on priority health and nutrition issues for evidence-based information utilization and technology transfer; effective public health emergency management; **establishing quality laboratory system**; and training public health researchers and practitioners for best public health interventions. As quality of health care service delivery through the provision of accurate, reliable and timely results that are critical for the correct diagnosis of diseases, treatment monitoring and prognosis of outcomes, EPHI would be working on laboratory quality management systems strengthening at the proposed BSL 3 laboratory such as quality manual, procedure and biosafety and biosecurity manual and procedures would be developed and implemented according to the international standards and all staff working in the BSL laboratory will trained on quality management system implementation. In addition, the laboratory will be participating in proficiency testing scheme in order to see the performance of the laboratory and the laboratory would be accredited by **ISO 15189:2012, Medical Laboratories-Requirements for quality and competence international standards** like other EPHI laboratories

2.9 Maintenance and Repair Procedure for the BSL3 laboratory

- The EPHI BSL3 lab director is responsible for ensuring that the physical components of the laboratory designed to contain the biohazards associated with the research are working properly and properly maintained (e.g., ventilation, filtration, sanitation, security). If the ventilation system or other physical containment component of the laboratory fails, work in the EPHI Biosafety Level 3 laboratory must be halted.
- Repair of the facility or laboratory equipment that requires entry into the laboratory by someone other than the laboratory staff must be authorized by the **Biosafety Officer before** work begins.
- Any time when the EPHI BSL-3 lab is closed for maintenance or repair, a laboratory clearance inspection must be performed by the EPHI biosafety staff before work is commenced. Once clearance is granted, no further work with biohazardous materials may be conducted until all maintenance and repair work is completed. A thorough inspection of the laboratory must be

conducted by the PI or designee to ensure that the laboratory is functioning properly before work with biohazardous materials may recommence.

- Routine maintenance that affects ventilation and containment provided by the facility or requires entry into the lab by non-laboratory staff shall be scheduled with biosafety and biosecurity unit of EHPI at least two weeks in advance. No maintenance or repair work shall begin without prior EH&S authorization. It is expected that biosafety and biosecurity unit of EHPI will conduct unannounced inspections during the maintenance.
- BSCs could be tested and certified annually and after installation, repair, or relocation in accordance with CDC guidance (CDC 2000b).
- Weekly tests of the required negative pressure for each room in the BSL-3 lab must be performed. (This test can be performed using a strip of tissue held in the opening of door held slightly ajar.) Problems must be reported without delay to Biosafety Officer. All readings must be logged and kept on file.
- Special containment systems, such as an exhaust HEPA filtration system must be tested and certified to meet the WHO, CDC standard no less than annually. These tests should be performed by an approved certification company.
- The PI at EPHI BSL3 lab must keep a log of all maintenance conducted by non-laboratory staff when the BSL-3 facility has NOT been closed for maintenance. The log should record:
 - type of work/maintenance completed (with enough detail so those unfamiliar with the work can reconstruct the sequence of work/maintenance events)
 - date of entry
 - names of workers
 - start time
 - completion time
 - disinfection technique for contaminated tools
 - Special personal protective equipment required to protect the workers (e.g., boots, heavy gloves, face shield etc.)
 - work order number
 - disinfection or other steps taken to protect maintenance workers

2.10 EPHI BSL 3 laboratory Staffing and Capacity Building

2.10.1 Staffing

The proposed BSL3 lab will have both professional and auxiliary staffs that are required for the continuous and proper operation of the facility. The BSL-3 facility will employ the following on a full-time basis, but not limited to except for the laboratory manager, the number of personnel will be determined based on the work load.

- Laboratory Director
- Laboratory scientist
- Laboratory quality Manager
- Biosafety and biosecurity Officer
- HVAC technician
- Electrical technician
- Equipment and instrument maintenance technician
- Well trained security staff
- Cleaners
- Waste handlers
- Incinerator Operators
- Wastewater treatment Plant Operators,

2.10.2 Roles and Responsibilities

The EPHI will have a strong biosafety and security unit to address and comply with regulations and recommendations for biosafety and biosecurity, and waste management as well as the health and safety of the staff, researchers, community, and environment. Roles and responsibilities of the staff in biosafety and biosecurity unit, wastewater treatment plant unit, incinerator facility and that of EPHI as a host institution are outlined below:

2.10.3 Ethiopian Public Health Institute (EPHI)

EPHI management will be responsible for overall management of the proposed BSL3 lab. To maintain regulatory compliance and to protect personnel, the community and the environment from biohazards, EPHI management will be responsible for:

- Appointing laboratory director, biosafety and biosecurity officer and other technical and support staff required for the BSL-3 lab
- Ensuring appropriate training is provided to personnel conducting research with biohazards or recombinant or synthetic nucleic acid materials.
- Ensuring that research conforms to the provisions of best international practices such as the *NIH Guidelines*, *BMBL*, *WHO Biosafety Manual* and *this ESIA*.
- Establishing and maintaining a *Biosafety Committee*
- Establishing and maintaining a health surveillance program for personnel.
- Reporting, when required, any significant problems, violations or significant research-related accidents or illnesses to pertinent Ethiopian Public Health and Environmental issues regulatory organs.
- Facilitating the preparation of guidelines, policies and plan relevant for smooth functioning of the lab
- Finance the construction/procurement of medical wastewater management facility and incinerator; and oversee the proper functionality of the medical waste management facilities

2.10.4 EPHI Biosafety and Biosecurity Committee

The Biosafety Committee will oversee the review, approval and oversight of biohazards in research activities at the EPHI campus. Specifically, the committee will be responsible for assessment of facilities in collaboration with the Biosafety Officer, and developing procedures, practices, and training of research personnel, or taking other steps necessary to assure compliance with WHO standard, *CDC Guidelines*, *the BMBL*, and other pertinent standards and regulations. To successfully carry out these responsibilities, the committee members should have sufficient knowledge and expertise in biomedical research practices and biosafety and biosecurity. The Committee has the authority to approve, require modifications to secure approval, disapprove, suspend or terminate research activities as required to assure compliance with applicable regulations and guidelines. Besides, Biosafety Committee will monitor ICWMP implementation, supervise the Infection control and waste management system of EPHI campus and the committee will be responsible to action for any deviation from the waste management procedure practices or malpractice during waste handling transportation, storage, treatment and disposal.

BSL 3 NRL Laboratory **Director**

EPHI will appoint a scientist and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with handling biohazards as a laboratory director. Responsibilities of the laboratory director:

- Accept direct responsibility for the health and safety of those working with biohazardous materials and/or select agents and toxins.
- Coordinate, perform and document the risk assessment for the biological agent(s)
- Develop and maintain the BSL3 Biosafety Manual in collaboration with the biosafety officer and other expertise
- Adhere to approved emergency plans for handling accidental spills and personnel contamination.
- Comply with permit and shipping requirements for biohazards. This includes permits, material transfer agreements, and other documentation for international, interstate and intrastate transport of genetically modified and biohazardous material.
- Develop specific biosafety Standard Operating Procedures (SOPs) for biohazards used in the laboratory.
- Ensure compliance by laboratory personnel with relevant regulations, guidelines, and policies.
- Ensure all appropriate personal protective equipment is provided and used. Ensure proper training, including refresher training, and instruction for laboratory personnel in safe practices and protocols, including, at a minimum, training in aseptic techniques and characteristics of the material(s) used.
- Ensure the integrity of the safety equipment (e.g. biological safety cabinets), maintain biological containment (e.g., purity and genotypic and phenotypic characteristics), and ensure correct procedures or conditions are followed to prevent a release of or exposure to recombinant or synthetic nucleic acid molecules and/or biohazards, select agents or toxins.
- Propose appropriate microbiological practices and laboratory techniques to be used for the research.
- Provide to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken.

- Immediately report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biosafety Committee
- Supervise laboratory staff to ensure that the required safety practices and techniques are employed. Correct work errors and conditions that may result in accidents, injuries, or the release of biohazards.
- Ensuring that personnel are adequately trained
- Ensuring that individuals working in the facility are experienced and proficient in handling the biological agents at the appropriate level of containment
- Ensuring that any visitor or contractor is escorted by an individual trained and approved to enter the facility
- Monitor and authorize access of all persons entering the BSL-3 laboratory. Access is limited to those who understand the nature of the biohazard, have adequate laboratory-specific biosafety training and agree to comply with all precautions.
- Oversee Medical Waste Management practices of the lab
- Ensure compliance by waste handler, wastewater treatment Plant and incinerator personnel with relevant regulations, guidelines, and policies of infection control and waste management.
- Ensuring that individuals working in the wastewater treatment Plant and incinerator are experienced and proficient in handling transportation, storage, treatment and disposal of waste including infection control,
- Ensuring that waste handler, wastewater treatment plant and incinerator personnel are adequately trained in waste management and risk management in wastewater treatment plant and incinerator facility respectively.

Laboratory Scientist

The responsibilities of the Laboratory Scientist

- Supervise and perform tests on various microbiological activities on a regular basis.
- Maintain knowledge on various testing methods and perform all manual and automated operations on various supplies.
- Perform tests on component samples, identify any contamination and perform analysis for appropriate source for same and initiate corrective actions.
- Perform various culture of microorganisms in isolation according to SOP

- Perform tests on all incoming ingredients and documents all records.
- Develop and prepare documents for all protocols.
- Perform molecular testing according to SOP
- Develop various testing processes for all raw materials and equipment and monitor all finish products.
- Investigate all issues and prevent any GMP problems on the procedure
- Maintain accurate records and perform tests on all activities conducted in laboratory.
- Develop and documents various microbiology laboratory processes and prepare final reports.
- Performs laboratory analysis and records findings and methodologies in appropriate hard or electronic file for future reference
- Assists initiates and guides junior researchers in adoption and adaptation of new laboratory methods and technologies
- Follow infection control and waste management procedure during handling of waste

Laboratory quality Manager

The responsibilities of the Laboratory quality officer

- Develop, Update, revise, and maintain the Laboratory's Quality Manual, Standard Operating Procedures, and other quality documents.
- Perform internal audits of the Laboratory, including both technical and quality systems audits.
- Perform and document corrective action, including follow-up monitoring to gauge the effectiveness of the corrective action.
- Perform analytical tests in the laboratory as assigned by the Laboratory director.
- Follow all quality assurance/quality control procedures as outlined in the laboratory quality manual
- Performing all QA/QC procedures for analytical tests
- Calibration of pipettes, thermometers, and other measuring equipment.
- Maintain current demonstrations of capability for all test procedures in the laboratory for which quality assurance oversight will be performed.
- Maintain training records for all laboratory staff, including demonstrations of capability.
- Schedule and successfully complete semi-annual proficiency testing for tests

- Ensure the fulfilment of the compliance by laboratory scientist, Biosafety officer, waste handler, wastewater treatment plant and incinerator personnel including other supportive staff with relevant regulations, guidelines, and policies of infection control and waste management.

Biosafety and biosecurity Officer

Biosafety and biosecurity officer is responsible for advising about, developing, implementing and supervising the safe and efficient collection, transportation, storage treatment, disposal and recycling of waste

- Advise on risk assessment for all proposed work with biological agents and the development of codes of practice
- Advise on waste disposal policy and arrangements u Advise on disinfection policy u Prepare contingency plans for action following accidents and incidents involving biological agents u
- Advise and assist management in investigations following accidents and incidents involving biological agents u Carry out periodic inspections of containment facilities
- Develop, implement, and maintain the institute's biosafety program to address issues of biosafety and biosecurity.
- Perform and review the required risk assessment to determine appropriate biosafety level and personal protective equipment (PPE) for handling recombinant and synthetic nucleic acid molecules or biohazards.
- Advise scientists/researchers on proper waste disposal methods.
- Assist scientists/researchers in the development of plans for preventing and handling accidental spills and personnel contamination.
- Investigate laboratory accidents involving biohazards and recombinant and synthetic nucleic acid molecules.
- Develop, implement, and maintain the institute's program for select agents and toxins.
- Perform periodic inspections to ensure that laboratory standards are rigorously followed.
- Promote regulatory compliance and a safe laboratory environment.
- Provide advice on laboratory security.
- Provide technical advice to laboratory director and the Biosafety Committee on research safety procedures.

- Provide technical advice to ensure compliance by waste handler. wastewater treatment Plant and incinerator personnel with relevant regulations, guidelines, and policies infection control and waste management including infection control.
- Provide technical advice to ensure that individuals working in the wastewater treatment Plant and incinerator are experienced and proficient in handling transportation, storage, treatment and disposal of waste
- Provide technical advice to ensure that waste handler, wastewater treatment plant and incinerator personnel are adequately trained in waste management and risk management in wastewater treatment plant and incinerator facility.
- Supervise the infection control and waste management system of EPHI campus and
- Ensure the implementation the Infection control and waste management procedure during waste handling transportation, storage, treatment and disposal
- Provide training and resources for the safe use and practices for those working with potential biohazards, and laboratory equipment.

Incinerator Operator

The responsibilities of the Incinerator Operator:

- Monitor and control the variations in waste compositions, the waste feed rate, and the combustion temperature
- Adhere to the proper Incinerator operating procedures
- Incinerator loading and prevention of waste spillage
- Follow Infection control and waste management procedure during waste handling transportation, storage, treatment and disposal
- Reporting Incinerator failures

Wastewater treatment Plant Operator

- Effluent sampling and management of data associated with BSL 3 NRL wastewater treatment facility
- Follow waste management procedure during waste handling transportation, storage, treatment and disposal
- Managing the inspection and cleaning of septic tanks and sand/media filters

- Inspection and maintenance of wastewater treatment facility
- Preparation of inventory report and procurement plan for the sustainability of treatment facility

Security Staff

The security department will be responsible for completing a risk assessment of the space, prior to the laboratory opening, and as needed. Security staff will also be responsible for monitoring the activity of the exterior locations of the storage space and lab and its surroundings.

Visitors, Vendors, and Contractors

Contractors must ensure that appropriate Personal Protective Equipment (PPE) is available for their own workers. All visitors, vendors, and contractors must:

- Comply with all security requirements and procedures.
- Be accompanied by an approved person at all times while in areas with select agents or toxins.
- Use Personal Protective Equipment (PPE) provided for them by the laboratory

Waste handlers

Waste handlers have principal Duties and Responsibilities: the Waste Handler is responsible for collecting, separating, containing, transporting, processing and/or shipping solid waste & regulated medical waste in accordance with relevant department and hospital procedures and all regulatory requirements

- Collects, separates, contains, labels and transports solid waste, medical waste & recyclable goods from generation points to specified collection location and incinerator
- Empties, relines, & cleans solid & medical waste containers according to procedures
- Segregates waste for containment prior to shipping offsite for incineration.
- Monitors available waste compactor capacity; alerting supervisor to ensure that unit is emptied before reaching full capacity.
- Operates solid waste and soiled laundry chute systems according to procedure
- Separates, contains, seals, labels, weighs, & stores high-risk infectious (red bag) waste to be incinerated
- Separates recyclables (glass, metal, paper, cardboard, etc.) for pickup. Operates baler according to department procedure for recycling cardboard/plastic

- Cleans and disinfects medical waste carts and totes. Maintains waste area facility in a clean and orderly condition; sweeps and cleans area at the end of each shift.
- Assures safe working conditions at all times as designated by the SOP; utilizes safety equipment and/or protective equipment as directed (i.e. safety gloves and eye protection), follows defined safety procedures.
- Follow waste management procedure during waste handling transportation, storage, treatment and disposal including infection control.
- Ensuring the safe and efficient collection, transportation, disposal and recycling of waste

Laboratory cleaners

These individuals perform different washing and cleaning activities outside the main BSL-3 laboratory this includes

- Cleans laboratory equipment, such as glassware, metal instruments, sinks, tables, and test panels, using solvents, brushes, and rags:
- Mixes water and detergents or acids in container to prepare cleaning solution according to specifications.
- Washes, rinses, and dries glassware and instruments, using water, acetone bath, and cloth or hot-air drier.
- Scrubs walls, floors, shelves, tables, and sinks, using cleaning solution and brush.
- May sterilize glassware and instruments, using autoclave.
- May maintain inventory reports and logs on cleaning materials and solutions.
- Follow waste management procedure during waste handling transportation, storage, treatment and disposal including infection control.

2.10.5 Training and Capacity Building

- The staff working within the containment laboratory must be well-trained in the concepts and practices on GMP and biosafety and biosecurity of the facility.
- All employees must have a clear understanding of any identifiable risks to their health arising from work and the actions to be taken in dealing with situations in which exposure may occur.

The level of training provided should be appropriate to the level of risk and the complexity of work being undertaken.

- Biosafety training must be regularly scheduled and presented to all persons who work in or who enter the Proposed Biosafety Level 3 laboratory. Comprehensive training must be provided for each new person prior to beginning work. Training continues for all laboratory staff with sessions presented one or more times in any one-month period. Training must focus on biosafety or other health and safety policies, practices and procedures to be followed for any activities with the laboratory. Enough instruction must be provided to cover the entire gamut of biosafety training at least once each year.
- All researchers receiving these biohazardous materials must be notified in writing of the risks associated with these materials, and of the need to handle the materials using BSL-3 practices and procedures. Documentation of biohazardous materials transfers must include the institution, Principal Investigator, date sent, nature and amount of material transferred, and the biosafety level required for this work.
- Training and agreement to comply must be documented (e.g., in a log or person-specific file). Visitors and maintenance personnel who enter the BSL-3 laboratory must be fully informed of the potential risks, required practices and procedures that they must follow. They must be instructed about the signs and symptoms of any and all biohazardous materials manipulated or stored in the laboratory
- Training should not be limited to those working at the bench. Laboratory managers, supervisors and safety advisors should be appropriately trained to ensure that they are competent, and they should maintain their professional competence by refresher training or other means. It is also necessary for auxiliary staff (e.g. cleaners and porters) and others (e.g. maintenance staff, external contractors and administrative staff) to receive enough and appropriate information, instruction and training about the hazards they may encounter when working in a laboratory. They should also be appropriately supervised while carrying out their work.
- Training should consider the breadth of work that is likely to be undertaken within a laboratory and the different levels of risk associated with the work, eg from working with samples suspected of containing biological agents to large-scale propagation and

concentration of biological agents. It may be necessary to gain experience of and become proficient in techniques and procedures using agents that are in a lower hazard group. Since laboratory workers may work in a number of laboratories throughout their career, the keeping of personal training records/portfolios (suitably endorsed by the relevant employer) provides a useful means of demonstrating professional development and competence to future employers.

- Training programs and protocols must be developed by the Biosafety Officer
- Laboratory workers should be trained to understand and tackle any kind of emergency situations within the containment laboratory without panic while ensuring their own safety first and ensuring that laboratory equipment is put into safe operating mode
- The BSL-3 Biosafety Officer and the Principal Investigator should receive appropriate training before the operation begins.
- Wastewater treatment plant and incinerator operators should receive appropriate training on waste management and risk assessment and management before the operation begins.
- Incinerator operators should be trained to understand and tackle any kind of emergency situations in incinerator without panic while ensuring their own safety first and ensuring that equipment is put into safe operating mode.
- Wastewater treatment plant operators should be trained to understand and tackle any kind of emergency situations in wastewater treatment plant without panic while ensuring their own safety first

2.11 Water Supply and Consumption

The source of water supply for construction and operation phases of the proposed NRL project is planned to be from the borehole water and Municipal water supply. The EPHI have its own borehole in the campus which is used as the main source of water supply. The municipal water is not reliable enough to be considered as a supply sole source and needs to be supplemented by the well. Currently, the daily ground water consumption of EPHI is estimated 1,500 litres/day. Of this 1,000 litres are used by the laboratories and 500 litres of water is used for miscellaneous activities such as gardening, toilet and showering. The rest of activities, such as kitchen and cafeteria rely on municipal water sources. Based on this the BSL3 NR complex is estimated to consume 1,000 liters. So that the total daily water consumption of EPHI campus would be estimated 2,500 litres/day.

2.12 Source of energy and Consumption

The main source of power supply for the proposed NRL project will be electric connection from the national grid. The EPHI campus is already connected to the public EEP electric network via four transformers providing power supply to the various laboratory and other facilities in the campus. In addition to the electric connection, there are about four standby diesel generators set with an Automatic Transfer Switch that provide alternative power supply during power blackout by the national grid.

2.13 Capacity and Experience of the Implementing Organization (EPHI)

2.13.1 Exiting Biosafety and Waste Management Practices at EPHI

EPHI's laboratories have Safety Manuals and SOP for waste handling and disposal. EPHI has regular training program on biosafety and biosecurity and waste management. Most of the staff are trained on biosafety and biosecurity and waste management. Staff working in the EPHI's laboratories are vaccinated according to the specific risk group. In addition, laboratory have been implementing quality management system including biosafety and biosecurity and some of the EPHI's laboratories (National Reference TB Laboratory, Microbiology laboratories, HIV) have already got accreditation on **ISO 15189:2012, Medical Laboratories-Requirements for quality and competence international standards** and EPHI Food Science and Nutrition Laboratory got accreditation on **ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories international standards**. Moreover, Microbiology laboratories has received a certificate of competency to perform Microbiology tests and Good Laboratory Practice from American Society for Microbiology (ASM) and Africa society of Laboratory medicine (ASLM). EPHI has been also operating Polio and influenza laboratories accredited by WHO. Since 2017, EPHI has Mobile BSL 3 lab which also helped to gain some experience in BSL3 lab.

All EPHI laboratories uses waste bags for waste collection. Sharp items are collected in safety boxes and special hard plastic bottles that designed for sharp. EPHI laboratories use colour coding (red or yellow bags for infectious waste) of HCW according to its type and use labelling system for the containers. After decontamination of wastes generated from laboratories and samples are collected and carried to the incinerators by personnel dedicated for waste handling using cart. The personnel use appropriate PPE during collection and transportation according to EPHI safety manual and waste management procedures. Infectious wastes from laboratory EPHI has been burned in Pyrolytic

Technology incinerators (See figure 9) that are designed for medical and pharmaceutical hazardous waste management. They can dispose of highly hazardous pathological waste and all medical waste. The pyrolytic incineration technology, also called controlled air incineration or double-chamber incineration, is a reliable and commonly used treatment process for health-care waste disposal.

The laboratories use autoclave to treat positive bacterial cultures, blood samples, syringes or any waste produced from testing. In EPHI's labs, liquid wastes, which contains pathogens, blood and hazardous chemical, except hazardous chemical they are treated with disinfectants, and finally it is disposed off into the septic tanks. Chemical, wastes are treated using neutralising/dilution methods. All non-infectious wastes are collected at the central waste collection area and then transported by the municipality vehicle transported to disposal sites.

2.13.2 Existing EPHI Incinerator

The EPHI's incinerators comprise a pyrolytic chamber and a post-combustion chamber and the waste is thermally decomposed through an oxygen-deficient, medium-temperature combustion process (800– 900°C), producing solid ashes and gases. The gases produced in this way are burned at high temperature (900– 1200°C) by a fuel burner in the post-combustion chamber, using an excess of air to minimize smoke and odors. The incinerators are properly functioning and have neither created disturbance nor nuisance to the local community around the area. EPHI's Incinerators located east part (See below the location in figure) of EPH, the surrounding place is open field, and store. Although EPHI has two incinerators, EPHI is currently using only one incinerator because the amount of waste generated at EPHI cannot be beyond the capacity of one incinerator, and the second incinerator has been working more than 20 years and it is getting old and the capacity of the existing incinerator to burn is 50kg per hours, EPHI is using as back up incinerator when the second incinerator is non-functional. The second incinerator has been working more than eight years and it has a capacity to burn 100 kg per hour and currently the incineration of waste is performed averagely 4 time a week. The detail specification and emission standard claimed by manufacturer of the incinerator is summarized tables 11 and 12. However no detail documented data/information of the existing incinerator is not found.

Table 11: Summary of emissions to atmosphere by the EPHI incinerators

S.N	Substance	Emissions to atmosphere*
1.	Particulate	30 mg/Nm ³
2.	CO	100 mg/Nm ³
3.	Sulphur Dioxide ³	200 mg/Nm
4.	HCL	30 mg/Nm ³
5.	Nitrogen Dioxide	300 mg/Nm ³
6.	Dioxins and Furanes	0.1 mg/Nm ³

*Smoke does not exceed No. 1 Ringelmann Scale

Regarding incinerator operator's capacity, there are 2 personnel working as operators and they are trained every year on incinerator operating, and preventive maintenance, waste management safety and PPE utilization, risks associated with incinerator and mitigations, spill management. Concerning incinerator maintenance, EPHI has a team of Medical Equipment maintenance working on performing preventive and curative maintenance for medical equipment, BSC, HVAC, incinerator and other related equipment so that the team has been performing preventive maintenance on annual based and according to manufacture recommendation including replacement of parts if required. In addition, the incinerators have been mechanical failures and most of the mechanical failures were maintained by EPHI bioengineers (trained by manufacture) with limited technical assistance from suppliers however there is no any evidence that showed the cost for the periodical maintenance of the incinerators since the spare part have been purchased by partners as support. Regarding monitoring and compliance records, there is no any evidence that showed regulatory body carrying out sampling and testing of emissions. There has been no ESIA conducted for the existing incinerators.

Table 12: Specification for Existing EPHI incinerator

Specification	Information
Model of incinerator	Incino B
Type of waste	Medical
Country of manufacture	United Kingdom
Year of manufacture	2008
Technology use	Pyrolitec
Capacity	100kg/hr
Fuel type	Diesel
Chimney Height	20m from the ground
Chimney weight	2500Kg

pre-treatment criteria	None
Number of burners	2 (Primary Chamber and Secondary Chamber)
Primary combustible temperature	750 to 850°C
Secondary combustible temperature	950 to 1100°C
Incinerator weight	19000Kg



Figure 9: Incinerators at EPHI for Waste Management

With regard emissions to atmosphere, one of the existing incinerators (which is eight years old) comply with UK environmental standards the emissions to atmosphere, summarized in table 11 above. As incinerators are properly functioning, there is no any complaint from community and it has neither created disturbance nor nuisance to the local community around the area. However, these incinerators do not meet the current acceptable emission standard such as EU and WB.

2.13.3 Existing Liquid Waste Management Practice at EPHI

Currently EPHI is managing liquid waste with the use of onsite waste treatment system. The treatment system mainly focused on the physical separation of scums and grits from the liquid waste and retention of microorganisms on porous organic materials packed in septic tank and sock away pits. In EPHI the treatment system is composed of one big septic tank//manhole that collectively receives waste from different laboratories of the institute. Once the waste is submerged in the holding tank, the waste is then flows into consecutives of double chambered septic tank and sock away pits. The

septic tank allows the waste to rest in the first chamber and so that the sludge precipitates. Once the sludge is retained, the effluent further enters into sock away pits. These sock away pits are packed with different porous sized gravels, cobbles and sands of different mesh size. Around 4 septic tanks and more than 4 sock away pits are used for liquid waste treatment in the current waste treatment of EPHI. The construction material used for these treatment units are pre-casted concrete materials. These materials were used to prevent infiltration of effluent into the ground water. The disposal of treated waste water and sludge from septic and sock away pits are currently outsourced to the Addis Ababa water and sewerage authority (Kaliti liquid waste treatment and Kotebe sludge management plants respectively).

Treated wastes have reduced level of organic or nutrient content, not to mention undetectable level of heavy metals. On the other hand, the toxicological investigation shows that the waste does not have lethal effect and the skin irritation test on rodents shows that the treated waste has no negative effect.

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2.13.4 EPHI's Capacity and Experience in biological research and diagnostic laboratories

EPHI has considerable experiences in biological research and diagnostic laboratories for several decades of years. Based on information provided by the EPHI National Laboratory Capacity Building director and Laboratory accreditation and Quality Improvement team, EPHI has operated BSL-2-equivalent laboratories for at least the last 50 years without any infections associated with their activities. Also, there were no unintentional releases to the environment or to the public associated with the EPHI biological research and diagnostic laboratories. In addition, EPHI also operates mobile BSL 3 laboratory for the last 2 years, and EPHI has a biosafety and biosecurity team working on biosafety and biosecurity at EPHI. There has been no incidence of laboratory-acquired infections recorded for EPHI workers. Based on extensive experience with the safe handling of biological materials at EPHI, it is projected that the diagnosis and scientific research to be conducted at the proposed BSL-3 facility would not result in significant impacts from normal operations to workers or the public as well as to the environment.

2.13.5 Experiences and Capacity of Ethiopia Managing BSL3 Laboratory

As clearly indicated in its Strategic Plan of 2015/16-2019/20, the Ethiopian Public Health Institute has long been planning to establish BSL3 capacity to ensure protection of health and safety of health

1 Information was extracted from the environmental public health laboratory of EPHI.

care workers when dealing with highly infectious and exotic agents that pose a high individual risk infections with severe to fatal disease in humans while investigating unknown etiologic agents of fatal diseases of epidemic proportion or conducting researches involving dangerous pathogens. The institute has thus considered the inclusion of this activity in the WB- Africa CDC Regional Investment Financing Program as a golden opportunity to realizing its longstanding vision. As part of this, the Ethiopian government has expressed a strong commitment and made necessary preparations including identification of site for state-of-the art Reference Laboratory construction with BSL3 suite in EPHI's existing campus. In addition, the government is committed to key aspects of designing, constructing and equipping the BSL3 laboratory facility in accordance with WHO biosafety standards and guidelines, and also in collaboration with other partners (CDC, WHO). The FMOH will recruit appropriate experts to ascertain the costs for the construction of the proposed facility as well as its maintenance and long-term operation. Even though there is a crucial need for having a brand new well established BSL3 Laboratory for better management of public health diseases and responses to outbreaks, Ethiopia has ample experience in the proper use and reliable management of BSL3 laboratories.

2.13.6 Mobile BSL3 Laboratory at Ethiopian Public Health Institute

Procurement and installation of Ethiopia's BSL3 mobile laboratory was made possible through an extraordinary technical and financial partnership between the Federal Ministry of Health (FMOH) and United Nations Country Team (UNCT) in Ethiopia. The acquisition of this mobile lab was decided at the time of the Ebola outbreak in West Africa from 2014 to 2016. This was part of multiple efforts undertaken by the FMOH to prevent, detect and contain an unexpected spread of the virus to Ethiopia.

Currently, the laboratory has standard Biosafety Manual, well trained laboratory professionals and Biomedical Engineers to manage the laboratory and its functions. The Biosafety Manual describes extra precautionary measures to be undertaken to protect the health and safety of the staff and the community through which the mobile lab passes or where it is stationed. EPHI will deploy this Mobile BSL3 laboratory to outbreak sites in the country usually in remote areas where there is limited access or no diagnostic capacity to support response to a disease outbreak.

In addition, EPHI has accumulated several years of experience in managing and operating many BSL2 laboratories located in its premises and has been implementing Biosafety and Biosecurity programs as part of GHSA initiative under the coordination and leadership of a dedicated Biosafety and

Biosecurity Team. The institute has also been implementing Pathogen Asset Control System (PACS) at relevant laboratories since the last three years and has systems in place for the proper management of liquid and solid laboratory wastes. Capacity for Biomedical Engineers have gone through rigorous training courses provided by Eagleson Institute in the USA on the installation, maintenance, validation and certification of Biological Safety Cabinets (BSC) of all types.

2.13.7 BSL-3 Laboratory located at National Animal Health Diagnostics and Investigation Centre

This laboratory is also one of the high containment laboratories in Ethiopia and located at the National Animal Health Diagnostics and Investigation Centre (NAHDIC) at the outskirts of Addis Ababa (25km) in Sebeta town and was established in 2009. NAHDIC is the referral and reference veterinary laboratory in Ethiopia. It is the Centre of excellence for animal disease surveillance, investigation, diagnosis and research which plays substantial roles in promoting export of animals and animal products, improvement of the livelihood of farmers and pastoralists, provision of professional support for investors involved in animal farming and transfer of technologies to stakeholders. This laboratory was established in response to the emergence of avian influenza and the need for getting prepared to detect the disease but also considering the importance of such facility for handling other high-risk Zoonotic diseases.

This laboratory has contributed a lot during Ebola outbreak in West Africa in ruling out suspected Ebola cases in Ethiopia. The investigations were routinely carried out by laboratory professionals from EPHI who have previously received comprehensive training in South Africa on the laboratory diagnosis of Ebola Virus. These professionals are currently managing EPHI's mobile BSL3 laboratory described above. Currently, NAHDIC itself has adequate well-trained laboratory staff with strong leadership and a robust system for the proper management of the BSL3 facility.

2.13.8 AU-Pan African Veterinary Vaccine Centre (AU-PANVAC) Laboratory

The Pan African Veterinary Vaccine Centre, an African Union Agency, was launched in 2004 in Bishoftu town of Ethiopia (42 km from Addis Ababa). The mission of the laboratory is to promote the production and use of good quality vaccines and reagents for the control and eradication of animal diseases in Africa. This laboratory is accredited to ISO17025 standards and is currently providing services in the Quality Control of Veterinary Vaccines produced in Africa and imported into Africa,

producing biological reagents for the diagnosis of various animal diseases and surveillance activities, facilitating the standardization of veterinary vaccines production, promoting the transfer of appropriate vaccine production technologies in Africa and providing technical support services to veterinary vaccines and quality control laboratories. Ethiopia, as a member of AU, is benefiting a lot from all services being provided by PANVAC including experience sharing on the safe use and management of BSL3 laboratory facility.

2.13.9 EPHI's commitment for sustainable financing of the operation and maintenance of the BSL3 facility beyond the project's life period

EPHI's proposal to the Africa CDC Regional Investment Financing Program as related to the designing, construction, furnishing and equipping of the National Reference Laboratory with a BSL3 suite is only to finance the activities including covering costs for initial validation, certification and full-fledged operationalization of the BSL3 facility. As such, EPHI is fully aware, committed and able to finance the operation and maintenance of this special facility beyond the project's life period.

3 Legal, Policy and Administrative Framework

This section describes the legal and regulatory requirements for environmental impact assessment and management in Ethiopia. Development projects in Ethiopia are required to meet and fulfil relevant legal provisions and policy frameworks that are intended to protect the environment and health of the society in general. The relevant national legislations and policy frameworks as well as the World Bank safeguard operational policies are reviewed and presented as follows.

3.1 Constitution and Relevant Policies in Ethiopia

3.1.1 Constitution

The constitution of the Federal Democratic Republic of Ethiopia (FDRE) provides the overriding principles for all legislative frameworks in the country. The concept of sustainable development and the environmental rights of the people are protected in the constitution by the articles that stipulate the rights of peoples in the country. The concept of sustainable development and environmental rights are enshrined in article 43, 44 and 92 of the Constitution of FDRE.

- **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 shall endeavour to ensure that all Ethiopians live in a clean and healthy environment. The design and implementation of programs shall 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 shall 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.

3.1.2 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 (EIA) 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,
- Is a legally binding requirement.

3.1.3 Environmental Proclamations

Proclamation 299/2002, Environmental Impact Assessment makes EIAs 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 EIAs,
- What procedure is to be followed in order to implement EIA

- The depth of environmental impact studies,
- Which projects require full EIA reports,
- Which projects need partial or no EIA 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 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 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.

EIA Directive 1/ 2008, Directive to Determine Projects Subject to Environmental Impact Assessment was issued to determine the categories of projects subject to the EIA Proclamation 299/2002. To this end, the EIA Proclamation is to be applied to the types of projects listed under these directives. The types of projects subject to EIA in the health sector are the construction of hospitals, which are part of the HSDP IV investment menu but are not included in the menu of ACRIFP-supported activities.

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 shall, 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 considering 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.

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

The 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 subject 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

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

EIA 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 EIA.

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.

3.2 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 government, and 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 occupational
- 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.

The National health care waste guideline outlines the categorization of health care wastes, the details of principles, procedures and actions that should be followed in managing the health care wastes on a daily basis, suggest safe collection, storage and transportation mechanisms for both within and out of the health care facilities, suggest the type of waste treatment options for both solid and liquid (infectious & hazardous) wastes including incineration options, recommend minimum health care waste management options/standards for different health care facilities and provide guidelines for monitoring systems and reporting procedures for HCWM at all levels.

3.3 International Conventions Ratified by Ethiopia

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
- Convention for the Protection of the World Cultural and Natural Heritage Paris, 23 November 1972.
- International Labour Organisation (ILO) Forced Labour Convention, 1930 (No. 29)
- ILO Equal Remuneration Convention, 1951 (No. 100)

Ethiopia is party to four international conventions, which directly or indirectly deal with pesticides production and use. 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.

Because Ethiopia ratified Stockholm Convention and Basel Convention, it has international obligations on proper management of hazardous wastes and minimization of dioxins emission. This has implications for the medical waste management and proper operation of incinerators.

3.4 World Bank Safeguard Policies and Guidelines

This project has been benchmarked against World Bank Group (WBG) standards. These standards, practices or guidelines are discussed below.

3.4.1 World Bank Operating Policies

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 environmental and social Safeguard Policies that WBG uses to examine potential environmental risks and benefits associated with Bank lending operations. The Bank's Environmental Assessment policy and procedures are described in Operational Policy/Bank Procedures - OP/BP 4.01. Detailed advice and guidance on the conduct of environmental assessment is provided publicly by the World Bank in its Environmental Sourcebook and updates. During project preparation, the World Bank examines the implications of the proposed project for a series of policies below:

The applicable World Bank safeguard policies as it applies to the proposed NRL BSL-3 project are summarized in table 13.

Table 13: 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 BSL3 National Reference Laboratory. The proposed project is Category A. It triggered OP 4.01. Thus, the present ESIA, ICWMP and Environmental and Social Management Plan (ESMP) have been prepared in response to OP/BP 4.01.
Physical and Cultural Resources (OP 4.11)	Yes	The proposed NRL BSL 3 project is going to be built within the premises of the EPHI, where there are no known physical and cultural heritage sites. However, since excavation will be conducted before constructing the NRL 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 proposed NRL BSL 3 project is going to be built within the existing vacant land spaces found within EPHI campus owned by itself. The project will not require acquisition of additional land and will not affect private properties. Thus OP /BP 4.12 will not be triggered by this project.
Natural Habitats OP/BP 4.04	No	The proposed NRL BSL 3 project is going to be built in the EPHI campus 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 NRL BSL 3 project is going to be built in the EPHI campus 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 NRL BSL-3 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-3 laboratory 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.

The construction, equipping and operation of the proposed BSL 3 laboratory will be restricted within the institute premises except for waste management/ pollutants generated that may go beyond the boundaries of the institute. The project will not directly affect ecosystems such as wetlands, forests, grasslands, etc. According to World Bank classification, the proposed BSL 3 NRL project is classified under Category A.

3.4.2 World Bank Guidelines

Under its “General EHS Guidelines, the World Bank has several guidelines, many of which are applicable to various components of the proposed project namely:

- Air emissions from onsite waste combustion units (“incinerators”)
- Hazardous waste management
- Noise
- Occupational health and safety (against biological and radiological hazards).
- Community health and safety including traffic safety such as during project construction or disease prevention (where incinerators emission waft into and affect not only local communities but also patients visiting or admitted in hospital including their attendants and the hospital staff).
- Construction and decommissioning.

While most of above WBG guidelines apply to the proposed project in one way or the other, in sections below are discussed four environmental, health and safety (EHS) guidelines, namely:

- EHS Guidelines - Air Emissions and Ambient Air Quality

- EHS Guidelines - Waste Management
- EHS Guidelines - Health Care Facilities
- EHS Guidelines - Hazardous Materials Management
- EHS Guidelines - Construction and Decommissioning

3.4.2.1 WBG EHS Guidelines: “Air emissions and ambient air quality”

These guidelines require projects with “significant” sources of air emissions, and potential for significant impacts to ambient air quality to prevent or minimize impacts by ensuring that emissions do not result in pollutant concentrations that reach or exceed relevant ambient quality guidelines and standards by applying national legislated standards (or in their absence, the current WHO Air Quality Guidelines, or other internationally recognized sources). Currently Ethiopia has no national air quality standards applicable to this project, specifically incinerator emissions however an adopted WHO air quality guideline (WHO, 2006) will be used for the project. The standards, however, make no mention of dioxins which potent cancer-inducing are, expected in incineration emissions. In these guidelines “significant” refers to sources which can contribute a net emission increase of one or more of the following pollutants within a given air shed particulate matter of size 2.5 microns (PM 2.5).

3.4.3 Comparison of National Requirements for HCWM and Occupational Health versus International Standards

The national requirements for hazardous waste management and occupational health and safety broadly derive 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 3 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.

In order 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 3 Laboratory project the WHO Laboratory Biosafety Manual (third edition, 2004) and the IFC EHS guideline for Health care Facilities appears to be directly applicable as international best practice requirements to the proposed BSL 3 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 3 laboratory.

With regard to 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*).

It is worth to note that the WBG EHS emission standards for PCDD/F from HCW incinerators are in agreement with the UNEP-POPs-BAT/BEP Guideline for Waste Incinerators.

3.4.4 Institutional Roles and Responsibilities ESIA

The relevant institutions responsible for the regulation of ESIA include the Federal Environmental Forest Climate Change Commission (EFCCC) and the Regional Environmental Authorities, in this case, the Addis Ababa Environment Protection Authority.

Federal Environment, Forest, and Climate Change Commission (EFCCC) is the lead agency responsible for formulating policies, strategies, laws, and standards to ensure social and economic development activities sustainably enhance human welfare and safety of the environment (Article 6, Proclamation 295/2002). The regulation of EIA is one of the key responsibilities entrusted to EFCCC. In this respect, the EFCCC is responsible for establishing a system for undertaking EIA in public and private sector projects. The EFCCC is responsible for developing a directive that identifies categories of projects likely to generate adverse impacts and require a full EIA, and for issuing guidelines that direct preparation and evaluation of EIA reports (Proclamation 299/2002, Articles 5 and 8).

In addition, the EFCCC is responsible for evaluating EIA reports of projects that need to be licensed and executed by the federal government and projects that are likely to generate inter-regional impacts. The EFCCC is also responsible for monitoring, auditing, and regulating implementation and

performance of such projects. The EFCCC holds primary responsibility for providing technical support on environmental protection and management to regional states and sector institutions.

Regional environmental bodies. Proclamation 295/2002 requires regional states to establish or designate their own regional environmental agencies. The regional environmental agencies are responsible for coordination formulation, implementation, review and revision of regional conservation strategies as well as environmental monitoring, protection and regulation (Article 15). Relating to EIA specifically, Proclamation 299/2002 gives regional environmental agencies the responsibility to evaluate EIA reports of projects that are licensed, executed, or supervised by regional states and that are not likely to generate inter-regional impacts. Regional environmental agencies are also responsible for monitoring, auditing, and regulating implementation of such projects. In case of Addis Ababa, the City Administration has established the *Addis Ababa Environment Protection Authority* in the early 1990s. The Addis Ababa regional EPA has also promulgated regulations that include “AACG Environmental Impact Assessment Regulation 21/2006”.

Sector environment units. The sector environmental units, stipulated in the Environmental Protection Organs Establishment Proclamation (295/2002), are to be established in every competent sector institution (i.e., the line ministry and regional sector agencies). These units have the responsibility of coordinating and implementing activities in line with environmental protection laws and requirements (Article 14, Proclamation 295/2002). Article 13 of the EIA Proclamation 299/2002 requires that public instruments undertake EIA. To this end, sector environmental units play an important role in ensuring that EIA is carried out on projects initiated by their respective sector institution.

Delegated authority. The EFCCC has delegated authority to sector institutions to ensure implementation of EIAs in their sector and to undertake EIA reviews. For instance, the Federal Ministry of Water and Energy is responsible for ensuring that an EIA is undertaken on water and energy projects and to review the EIA. This delegation has been communicated to sector ministries through an official letter sent by the EFCCC.

The organization of additional environmental and social management roles and responsibilities within the health sector are described below.

Table 14 summarizes the roles and responsibilities of institutions involved in environment and social management in Ethiopia. Identification of institutional roles and responsibilities takes into account potential environmental implications of ACRIFP-supported activities and the requirements.

Table 14: Institutional Roles and Responsibilities

Entity	Roles and responsibilities for environmental and social management
Federal Environment, Forest and Climate Change Commission	As the national entity for environmental management, EFCCC is responsible for: <ul style="list-style-type: none"> • Enforcing and ensuring compliance to the EIA proclamation on Federal Licensed projects • Reviewing EIAs and monitoring the implementation of EIA recommendations on Federal Licensed projects • Regulating environmental compliance and developing legal instruments that ensure the protection of the environment, • Coordinating, advising, assessing, monitoring and reporting on environment-related aspects and activities.
Federal Ministry of Health, Public Health Infrastructure Directorate (PHID)	<ul style="list-style-type: none"> • Monitoring implementation of mitigation actions by contractors • Coordinating and providing training and capacity building where planned • Periodically report to FMoH about implementation of the ESMP
Ministry of Water and Energy	Prevent and control pollution of water resources.
Addis Ababa Labour and Social Affairs Bureaus	<ul style="list-style-type: none"> • Enforce occupational health and safety in work places in line with its mandates, roles and responsibilities.
Addis Ababa Environment Protection Authority	<ul style="list-style-type: none"> • Enforcing and ensuring compliance to the Regional EIA proclamation on projects licensed by the Addis Ababa Administration. • Reviewing EIAs and monitoring the implementation of EIA recommendations of projects licensed by the Addis Ababa Administration • Regulating environmental compliance and developing legal instruments that ensure the protection of the environment.
Ethiopian Public Health Institute (EPHI)	<ul style="list-style-type: none"> • As project owner provide necessary resources, guidance and supervision for preparation of the ESIA/ESMP. • Provide necessary resources, guidance and supervision for implementation of the ESIA/ESMP recommendations during operation period of the BSL-3 Laboratory.

The **Food Medicine Health Care Administration and Control Authority** is an autonomous entity under the Ministry of Health. The FMHACA has the mandate, as per Proclamation 661/2009, to regulate:

- Healthcare practice;
- Healthcare premises, which includes healthcare facilities, food establishments, medicine facilities, health-related facilities and port inspection sites;
- All health professionals;
- Healthcare products from production to consumption of medicines, medical equipment and devices, food and food supplements, herbal products, cosmetics, AND complimentary and traditional medicines.

These regulatory activities are decentralized and function throughout all regions and woredas of Ethiopia. At the regional, zone, and woreda levels, these regulatory activities are implemented through the **Health and Health-Related Services and Product Regulation Core Process**.

The **Health Promotion and Disease Control Directorate** coordinates health initiatives in the region states. The Directorate provides targeted support to these region states and works as a liaison of the federal MOH. The Directorate offers short- and long-term technical support to these regions by assigning experts to support districts in these regions. The Directorate is responsible for coordinating environmental health, hygiene, and sanitation activities of the Ministry at the national level. The Directorate serves as the sector unit for environmental management within the Ministry, fulfilling the requirements of Proclamation 295/2002 that stipulates the establishment of environmental units within sector organs. Moreover, the Directorate leads the Ministry's participation in joint initiatives with the EFCCC, including strengthening environmental health interventions in line with the Libreville Declaration and mainstreaming the climate change agenda in the health sector.

The healthcare delivery process is one of the eight core processes being implemented by FMOH. This core process has two components: health promotion and disease prevention, and curative and rehabilitation services. The **Medical Services Directorate** is responsible for the latter and is mandated to ensure quality, affordable, and accessible medical services nationwide. This Directorate, in line with its role in infection prevention and health safety, coordinates the National Infection Prevention and Patient Safety (IPPS) Advisory Working Group. This Advisory Group was responsible for development of the National HCWM Strategic Action Plan 2012-2015.

This National HCWM Strategic Action Plan focuses on achieving four objectives:

- Implement and support revision of the legal and regulatory frameworks for HCWM;
- Standardize HCWM practices and equip health care facilities;

- Improve institutional and management capacities of health care facilities as well as woreda, zonal, regional and central health authorities;
- Establish a proper HCWM Monitoring Plan for health care facilities at woreda, zonal, regional and federal levels.

The Medical Services Directorate, with support from the Directorate, has been given the responsibility of monitoring and supervising implementation of the National HCWM Strategic Action Plan. The National Infection Prevention and Patient Safety (IPPS) committees have been formed at the regional health bureau, zonal health department and woreda health office level under the Curative and Rehabilitative or Health Promotion and Disease Prevention Core Processes. The IPPS committees lead implementation of the Plan and ensure that there is input from the environmental health officer who is a member of the committee and who coordinates healthcare waste management activities.

The Public Health Infrastructure Directorate (PHID) ensures efficient and effective use of essential public health services, human resources, health information technology and infrastructure necessary for accessible, and quality health service delivery at the national level. With respect to its work pertaining on health facility expansion and rehabilitation, the Directorate:

- Manages health facility construction contracts and supervises building sights;
- Designs health facilities and allocation of medical equipment;
- Sets construction standards and provides information and consultancy services regarding construction of health facilities;
- Coordinates and oversees safe, secure and environmentally sound operation and maintenance of appliances, including air conditioners, boilers, stoves, water supply and sewerage systems and medical equipment;
- Develops facility standards for essential civil works.

This Directorate is responsible for ensuring that the design of all facilities incorporates provisions for addressing environmental impacts, including facilities for infectious and hazardous healthcare waste management. The Directorate is responsible for developing environment, health and safety standards for contractors, incorporating such requirements in healthcare facility construction contracts, and monitoring compliance of contractors to these requirements. The Directorate's facility design for health Centres is stringent when considering the environmental aspects of incinerators included in the design developed by the Directorate.

The Ethiopian Public Health Institute (EPHI): the former Ethiopian Health and Nutrition Research Institute (EHNRI), is re-established as an autonomous federal government institute having its own legal personality as the main government body in charge of three main tasks as expressed in the regulation number 301/2013: Research, based on national public health research agenda on priority public health and nutrition issues, generate, translate and disseminate scientific and technological knowledge; surveillance, for the early identification and detection of public health risks and prevent public health emergencies through adequate preparedness, alert, timely information during public health emergency, respond effectively and timely and ensure rapid recovery of the affected population from the impact of public health emergency; Referral diagnostic and analytical tests and support the capacity building of health and food science laboratories at the national level for quality laboratory services.

EPHI Director General is the Chief Executive Officer and there are two Deputy Directors General, that is, the Public Health Emergency Management (PHEM) Deputy Director General and the Research Technology Transfer (RTT) Deputy Director General, work hand in hand with the Director General with clearly defined responsibilities. The institute management committee comprises all directors of directorate and administrative services. It is the main link between the top management and institute staff and meets once in a week regularly. The Director General is the overseer of all the services and the Directors are responsible for their respective directorate matters, including human resource management and financial matters. The Management Committee, with the directorates' directors having an advisory role, makes the day-to-day operational decisions of the institute.

The EPHI will be responsible for running the proposed BSL-3 NRL Laboratory during its operational phase. The role of EPHI during operation and verification of the proposed BSL-3 laboratory including Occupational health and safety risk management are outlined in detail in **section 2.5**. As the daily operations of the proposed BSL -3 NRL will be managed by EPHI, it will also assume the responsibilities for managing the health and safety procedures of the proposed laboratory, proper operations of the health care solid waste incinerators and wastewater treatment plant, and the overall management of environmental and social risks that may occur during the operational phases of the proposed project. The Management of EPHI will put in place the necessary staffing dedicated to supervise and control the environmental and social soundness of the daily operations of the laboratory.

4 Environment and Socio-Economic Baseline

This section describes environmental and social baseline conditions of the area in which the proposed NRL project is to be located and in which potential impacts from implementation of the project may be experienced. The description is designed to enable identification of particularly sensitive receptors and resources around the proposed site that may be vulnerable to impacts arising from the project.

4.1 Biophysical environment baseline

4.1.1 Topography

Addis Ababa lies at an elevation of 2,200 metres and is a grassland biome, located at 9°1'48"N 38°44'24"ECoordinates: 9°1'48"N 38°44'24"E. The city lies at the foot of Mount Entoto and forms part of the watershed for the Awash River. From its lowest point, around Bole International Airport, at 2,326 metres (7,631 ft) above sea level in the southern periphery, Addis Ababa rises to over 3,000 metres (9,800 ft) in the Entoto Mountains to the north.

Addis Ababa is built on the steep escarpment of Mount Entoto and stretches farther to the south, where it turns out to be of a gentle slope nature and relatively of lower altitude. According to the Atlas prepared by the Addis Ababa City Administration Integrated Land Information Centre, the general elevation of city ranges from as high as 3020masl on the top of Mount Entoto to as low as 2000 masl in the river valleys of the southern edge in Akaki-Kaliti (see figure 10 below).

The topography of Gulele sub-city and the project area have a slope of undulating nature and ranges from 2700 to 2806m above mean sea level. The topographic condition of the project site can be expressed based on qualitative and quantitative values. The qualitative approach describes the project site's relative topographic feature with respect to the local topographic condition. With this respect, the project site is categorized under the flat topography. The quantitative approach describes the altitude of the project site measured from the universal reference point, the sea level.

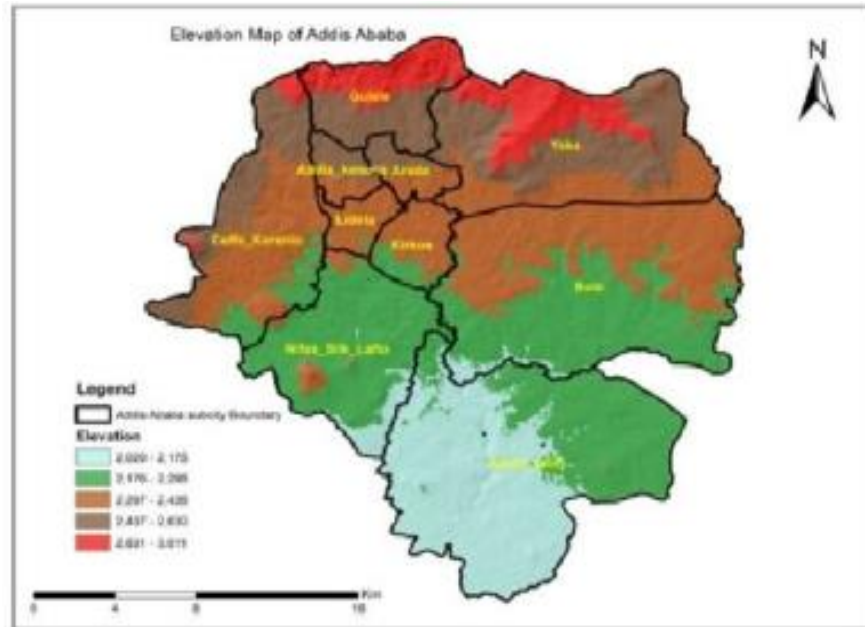


Figure 10; Topographic Map of Addis Ababa

4.1.2 Climate

The city has a subtropical highland climate and it has a complex mix of highland climate zones, with temperature differences of up to 10 °C (18 °F), depending on elevation and prevailing wind patterns. The high elevation moderates temperatures year-round, and the city's position near the equator means that temperatures are very constant from month to month. As such the climate would be maritime if its elevation was not taken into account, as no month is above 22 °C (72 °F) in mean temperatures.

Mid-November to January is a season for occasional rain. The highland climate regions are characterized by dry winters, and this is the dry season in Addis Ababa. During this season the daily maximum temperatures are usually not more than 23 °C (73 °F), and the night-time minimum temperatures can drop to freezing. The short rainy season is from February to May. During this period, the difference between the daytime maximum temperatures and the night-time minimum temperatures is not as great as during other times of the year, with minimum temperatures in the range of 10–15 °C (50–59 °F). At this time of the year, the city experiences warm temperatures and a pleasant rainfall. The long wet season is from June to mid-September; it is the major winter season of the country. This period coincides with summer, but the temperatures are much lower than at other times of year because of the frequent rain and hail and the abundance of cloud cover and fewer hours of sunshine. This time of the year is characterized by dark, chilly and wet days and nights. The autumn which follows is a transitional period between the wet and dry seasons.

4.1.3 Soil and Geology

Though there are a number of soil types found in the Ethiopia, the major soil types found are Nitosols, Vertisols, Cambisols, Acrisols, Luvisols, Lithosols, Aluvisols, Arenosols and Regolsols. In general, most of the soils are of good agricultural potentials. However, soils on the highlands (such as Addis Ababa) of the country have been subjected to serious erosion due to human activities. Although there is different type of soils, expansive soils are predominant in Addis Ababa. These soils are either black or grey in colour with thickness ranging from few centimetres to several meters. Soil map of Addis Ababa as well as field observation reveal that the site is dominantly covered with black cotton soil. The black cotton soil cover above the weathered rock is with an average of 0.8m thickness. The black cotton soil in the site is characterized with high plasticity and high degree of swelling. The black cotton soil horizon is thin along southern and western peripheries of the area around the project location where rocks are outcropped because of erosion.

4.1.4 Ambient Air Quality

The ambient air quality of Addis Ababa city is not regularly monitored. Thus, data on ambient air quality are scares. However, there are few studies that show emergence of air pollution problem in the city. A study on state of air pollution was conducted in 2012 by the Addis Ababa Institute of Technology by taking twelve traffic congested sites in the City. The study found that PM_{2.5} measured values exceeded the WHO standard at all sites. Another study (Awoke et.al. 2013) conducted in 2011 in Addis Ababa (using bio-monitoring; lichens as pollution indicators) near major bus stations indicated that the ambient air of those corners of the city was highly polluted mainly due to heavy traffic.

Measurements carried out as part of the baseline assessment for the present proposed NRL project at selected locations in EPHI and the project area indicated an environment free from carbon monoxide, ammonia and nitrogen oxide emissions as indicated in Table 15.

Table 15: Air quality at the proposed project site

Latitude	Longitude	O ₂ (%)	PID (ppm)	Particulates (µg/m ³)	LEL (%)	PID (ppm)	Remark
		20.9	1.2	25			Southwest corner of Sample collection area

4.1.5 Noise

The major sources of noise in Addis Ababa city is transportation and human activities. The most common form of noise pollution is from transportation, principally motor vehicles along high way. As EPHI is found near Swaziland Street, this Street is a major thoroughfare with multiple lanes of traffic going in both directions and a roundabout on the southwest corner of the EPHI campus, resulting the most common form of noise pollution from traffic activities.

4.1.6 Flora and Fauna

Addis Ababa city fundamentally possess an urban environment. The built-up area in Addis Ababa city comprises, however, of terrestrial vegetation that are grown as fencing shrubs, ornamental trees on open spaces, street side and median trees, recreational parks and patch of indigenous trees in religious places such as churches. Moreover, the upper catchment of Addis Ababa City, mainly along the Entoto mountain chain, has plantation forest composed of eucalyptus tree. Study reports indicate that the amount of plantation forest cover in five upper catchment Sub-Cities of Addis Ababa comprising Gulele, Yeka, Kolefikeranyo, Akaki-kality and Bole Sub-Cities consist of 10, 14.9, 5, 0.42 and 4.84 square kilometre areas of plantation forest respectively. On the otherhand, the other sub-cities of Addis Ababa such as Nefas selk lafeto, Kirkos, Ledeta, Addis Ketema and Arada did not have any plantation forest cover (Fikirte et.al, 2015).

With regard to flora and fauna in the immediate zones surrounding the EPHI and the project area where the proposed NRL shall be build, one can hardly see any remnant of natural vegetation in general except for the few ornamental and common eucalyptus trees and fencing trees/shrubs. There is no recreational park or animal sanctuary around the project areas that could be impacted due to the implementation of the proposed NRL project. Being an urban core area, it couldn't provide a good habitat to support diverse wildlife species. As a result, there are no rare or endemic animal species known to be in the Project area.

4.1.7 Surface Water Resources

The main surface water resources present in and around Addis Ababa are the Akaki Rivers which traverse the city from north eastern and north western parts of the city down to the southern plains culminating at Lake Aba-Samuel. The Gulele area is one among those which form the upper catchment and head waters/springs for the Akaki River Basin. The catchment area of the Akaki river

basin is divided into two sub-catchment areas. These are the Great Akaki River (Eastern and South eastern) sub-catchment and the Little Akaki river (Western and south western) sub-catchment. Within the Akaki river basin, there are a number of perennial rivers. The most important ones are Big Akaki, Little Akaki and Kebena. The NRL project area is situated within the upper catchment of the Akaki river basin. It is observed that the great and little Akaki are also the major carriers of wastes released into it and its small tributary streams. The wastes entering into the river systems include municipal and industrial wastes of solid and liquid nature. As a result, the rivers are observed to sustain continued water pollution as has been confirmed by numerous studies. The Akaki Rivers and its catchment belong to the Awash Basin.

4.1.8 Water Supply

Addis Ababa has not yet reached full coverage of water supply or sewerage, and also faces significant and growing water scarcity. It is estimated that only 44% of the population has access to clean water 23 and 30% has access to piped sewerage or vacuum truck service. Addis Ababa has two sources of water – surface and groundwater. Surface water comes from 3 dams that feed into 2 treatment plants such as Geffersa, Legedadi, and Dire Dams (see figure 11-13 below). They are in the east and northwest of the city and flow to the city with gravity. There are 3 primary well fields for groundwater extraction with a total of about 50-60 wells. They are in the southeast section of the city. Water is collected into tankers via gravity and treated, and then pumped to the city. The per capita distribution is estimated to be around 40 litres /day, well below the city’s goal of 110 litres /day. Ababa Water and Sewerage Authority (AAWSA) is currently supplying water to certain parts of the city on a rotating basis, with some areas receiving water only two days a week through distribution lines or water truck.

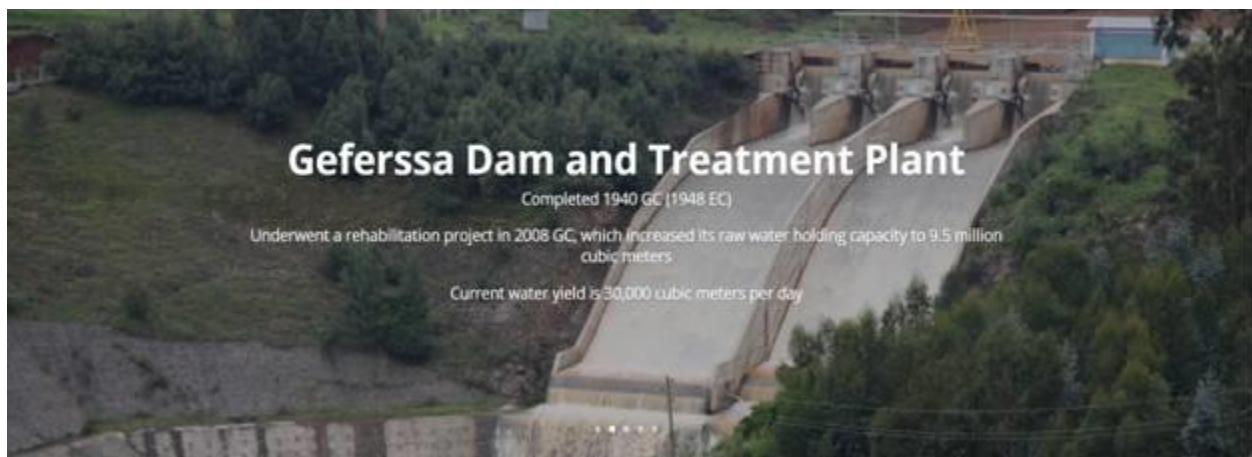


Figure 11: Geferssa Dam and treatment Plant

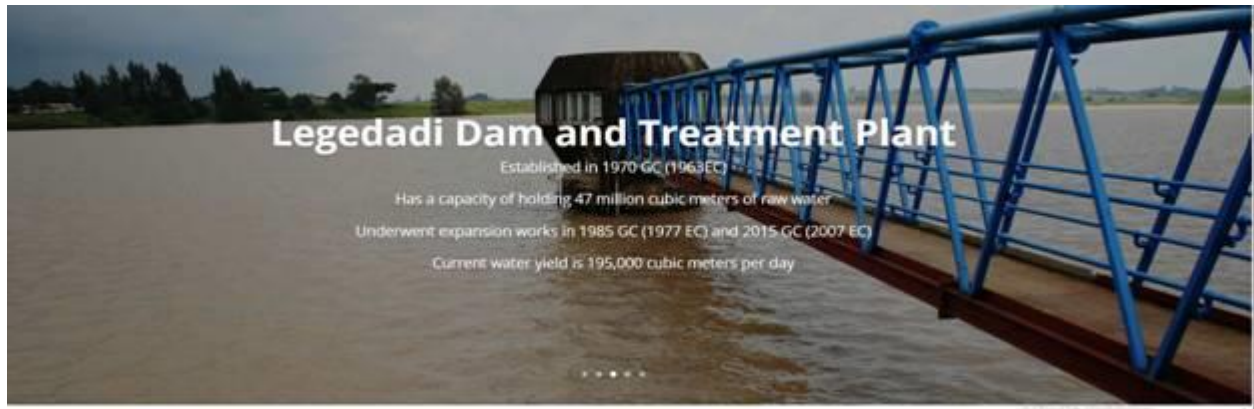


Figure 12: Legedadi Dam and Treatment Plant

The groundwater is from a volcanic aquifer, making recharge from retention ponds infeasible. In addition to City water supply, EPHI has been using the groundwater and has a reservoir tank in case of problems with the supply system; the institute can still get access to water. The up and down wrapping of underground rocks accompanied by faulting, shearing and jointing has influenced the drainage pattern in the district to form a dendrite drainage pattern



Figure 13: Dire Dam and Treatment Plant

4.1.9. Waste management facilities

The Addis Ababa City Administration, UNDP MDG Carbon and UNDP Ethiopia Country Office worked together to support the development of the Repi Landfill Gas Clean Development Mechanism (CDM) Project under the United Nations Framework Convention on Climate Change (UNFCCC). This project is responsible to convert non-hazardous solid waste generated in the city to power energy. It is close to the existing landfill which introduce better management practices of municipal solid waste in Addis Ababa. This includes modern technology, sorting facilities for recycling and collection of municipal solid waste and the opening of a new landfill site under best practice management standards. The project demonstrates a combination of economic benefits, social benefits, and environmental benefits. Regarding hazardous medical solid waste, there is no central waste treatment

plants in Addis Ababa. But there is a new centralized incinerator built by ministry of health in Adam town 90 km away from Addis Ababa designed for incineration of pharmaceutical and medical waste. This approach would reduce health and environmental pollution risks that would arise from several inefficiently managed and run incinerators or burning pits/burials pits. However, the major drawback of this approach is that it will require a transportation infrastructure and, there is a risk during transportation of the waste from BSL 3 labs to centralized Incineration place as well as expensive.

4.1.9 Water Treatment and Drainage

Sewage disposal is the responsibility of the Addis Ababa Water Supply and Sewerage Authority (AAWSSA). It operates with seventeen wastewater treatment plants. The main ones are Kality and Kotebe and in twelve condominium areas. The sewer line is connected to Kality treatment plant and sludge is transported to Kotebe treatment plant using vacuum trucks that empty septic tanks. The treatment involves circulation of sewer in various ponds for about 30 days in order to make the level of BOD fall below 5mg/L Addis Ababa has two main sewage treatment plants which are Kality and Kotebe treatment plant. The Kality had capacity of 7,600 m³/day wastewater treatment however, according to Addis Ababa Water and Sewerage Authority (AAWSA), currently the project expansion has been upgraded to capacity of 100,000 m³/day to treat wastewaters with the support of the World Bank and the Kality treatment plat had an EIA that approved by Ethiopian Environmental Forest Climate Change Commission as well as by World Bank. Besides, it is supervised and monitored by Federal and Addis Ababa Environmental Forest Climate Change Commission regularly for fulfilment the requirements and regulation.

The other main treatment plant is called Kotebe treatment plant, it receives only sludge from vacuum trucks that empty septic tanks. The Kotebe treatment plan was established 22 years ago by Addis Ababa Water Supply and Sewerage Authority with objective to treat and dispose of sludge collected form the city with the capacity to treat volume of 85,000 m³/day. In addition, Addis Ababa Water Supply and Sewerage Authority introduces expansion project to increase the capacity and efficiency of the treatment plat by additional 80,000 m³/day in the coming few years. According to the Addis Ababa Water and Sewerage Authority, the Kotebe treatment plat had an EIA that approved by Ethiopian Environmental Forest Climate Change Commission, however we did not get documented EIA from the organization as it was established several years ago. But the current expansion the treatment plan has an approved EIA document.

Addis Ababa city administration provided legal certificate including site plan to Addis Ababa Water Supply and Sewerage Authority to establish and manage the Kotebe treatment plant. The treatment plant is established in the territory norther part of the city far away from residential and business centre and there is no any sensitive area receptors around the treatment plant. In addition it is supervised and monitored by Federal and Addis Ababa Environmental Forest Climate Change Commission regularly. In general the Kotebe treatment plat has been performing according to the Ethiopian National Environmental Proclamation 300/2002, Environmental Pollution Control, and regulation.

In addition to this, there are also several decentralized treatment plants that primarily serve condominiums. Industries are not connected to the system, they handle their own treatment and it is overseen by the Addis Ababa Environmental Forest Climate Change Commission.

Thus, until sewer line is connected to those treatment plants, the wastewater and wastewater sludge generated in EPHI would be transported to those treatment plants by using sewage trucks that empty septic tanks. The sludge would be transported using Addis Ababa Water and Sewerage Authority Sewage trucks and the transportation would be managed by Addis Ababa Water Supply and Sewerage Authority



Figure 14: Addis Ababa Water and Sewerage Authority Sewage trucks

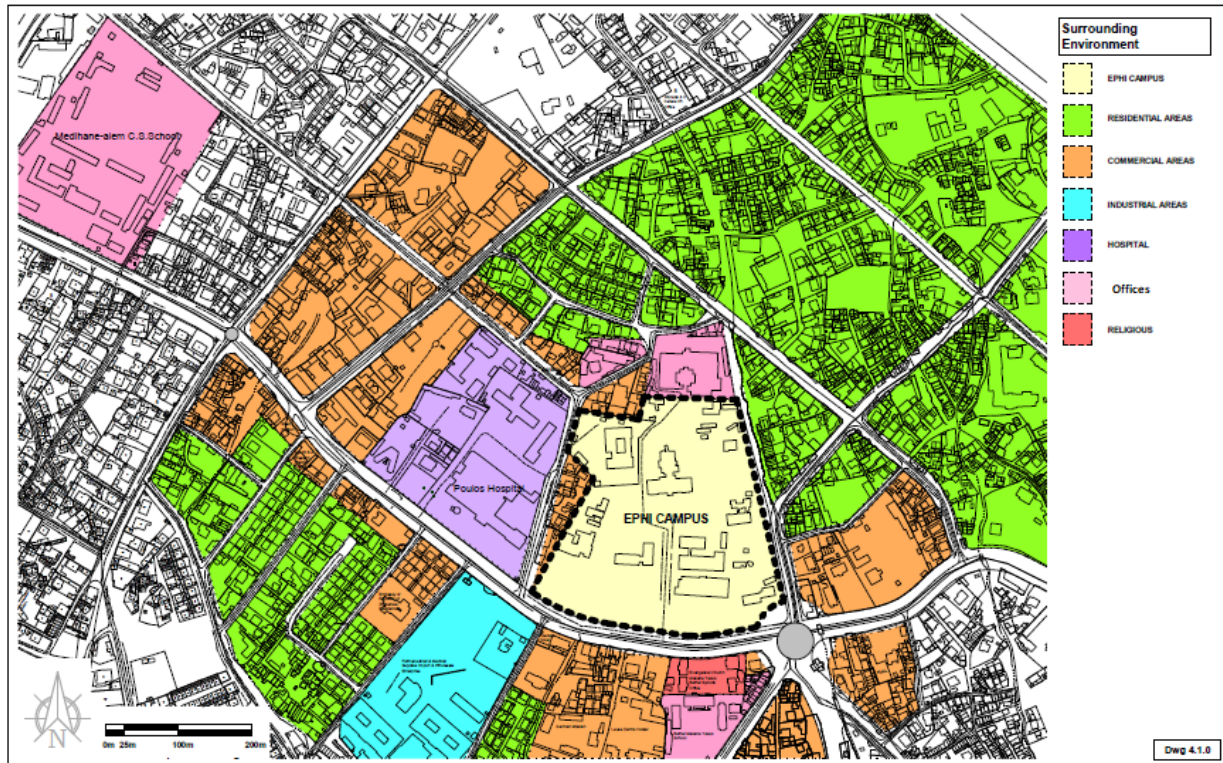
4.2 Socio-Economic Baselines

4.2.1 Population and Demographic Characteristics

Addis Ababa is the capital city of Ethiopia and it holds 527 square kilometres of area. It is also the largest city in the country by population, according to 2007 population census, a total population of 2,739,551 inhabitants and 662,728 households were counted living in 628,984 housing units in Addis

Ababa, which results in an average of 5.3 persons to a household. Gulele Sub city has a population of 267,381 out of which 48.35% are male and 51.65% female. Although all Ethiopian ethnic groups are represented in Addis Ababa, the largest groups include the Amhara (67.04%), Oromo (19.00%), Gurage (16.34%), Tigrayan (5.18%), Silt'e (2.94%), and Gamo (1.68%). Languages spoken include Amharic (71.0%), Oromiffa (10.7%), Gurage (8.37%), Tigrinya (3.60%), Silt'e (1.82%) and Gamo (1.03%). The religion with the most believers in Addis Ababa is Ethiopian Orthodox with 74.7% of the population, while 16.2% are Muslim, and 7.77% Protestant. (CSA 2010). The city has through recent years seen a strong annual growth rate, and population counts. In 2017 the population of the city is estimated about 4 million.

The proposed BSL 3 NRL project will be situated within the campus premises of the Ethiopian Public Health Institute (EPHI) which is found in Gullele Sub City, Woreda 09, on Swaziland Street. Being an urban core, the Swaziland Street is dominated by houses and buildings occupied by commercial and business entities. The EPHI campus is surrounded by mixed residential and business areas such as Ethiopian commercial Bank branch (about 1.5 km far away from EPHI incinerator facility), Ethiopian pharmaceutical supply Agency (about 1 km far away from EPHI incinerator facility), religious coordination office (1 km far away from EPHI incinerator facility), shops (about 1 km far away from EPHI incinerator facility), pharmacies (about 1 km far away from EPHI incinerator facility), and health care facilities (about 2 km far away from EPHI incinerator facility), are common on this woreda, EPHI is being the oldest Centre have close proximity to Paulos Hospital Millennium Medical College (but the Medical College school is far about 1 km away from EPHI incinerator facility). Although infectious, it was estimated to be about 1 kg (2 kg per week). Although there Sensitive receivers such as residential, educational institution; healthcare facilities; shops sensitive to pollution are identified, there are no sensitive receivers within and in the vicinity of EPHI. As per the discussion conducted with woreda city administration, forest and environmental protection office, community leader, and community representatives.



Within the EPHI campus, the buildings adjacent to the selected site of the project are as follows:

- To the North - the Vaccine Production facility
- To the East - the new training Centre and meeting hall
- To the West – The HIV and other, smaller laboratory buildings
- To the North-West – The CDC office building
- To the South West the suspect-rabid dog Quarantine building

4.2.2 Education

In Ethiopia there are more than 50 government and private universities and colleges. Addis Ababa University is the first University in Ethiopia and it is one of the higher institutions in the country located in Addis Ababa. In addition, there is 1 government and 2 private Universities and several colleges including teaching hospitals. All University and college’s mandate are to provide skilled human resources in the areas of education, health, engineering, agriculture, technology, research, peace and security. Every year about 100, 000 candidates are graduated from these institutions in the country (FMoE, 2015).

4.2.3 Healthcare Services

According to FMOH health and health related indicators report (FMOH 2017/18), in Ethiopia there are 338 hospitals owned by government and 43 hospitals owned by private organizations and a total of 4063 government health Centres as well as 3867 private primary, medium and specialty clinics. In Addis Ababa there are 12 government hospital and 25 private NGOs hospitals and a total of 98 health Centres and 980 primary, medium and specialty clinics owned by private sector. Among the 12 hospitals, seven of its provide referral and advanced specialty services for all patients referred for advanced treatment and care from across the nation.

4.2.4 Economic Activities and Employment

Addis Ababa is home to 25% of the urban population in Ethiopia and is one of the fastest growing cities in Africa. It is the growth engine for Ethiopia and a major pillar in the country's vision to become a middle-income, carbon-neutral, and resilient economy by 2025. Addis Ababa's economy is growing annually by 14%. The city alone currently contributes approximately 50% towards the national GDP, highlighting its strategic role within the overall economic development of the country. Despite the strong economic growth trends, Addis Ababa faces significant development challenges. For example, unemployment and poverty levels in Addis Ababa remain high, estimated at 23.5% and 22% respectively. More than one in four households report an unemployed adult compared to one in 10 households in other urban areas, and the informal sector employs about 30% of the economically active labour force in the city (WBG, 2015).

Moreover, the physical development patterns witnessed in recent years are driving up the cost of infrastructure delivery. Addis is expanding in a sprawling manner, with growth in urban extent outpacing population growth. The result of this growth is an estimated 46% of vacant or underutilized land. At the same time, the city Centre has extremely high density (up to 30,000 people per km), concentrating around 30% of the population on 8% of the land, generally with poor living conditions. Recognizing the strategic importance of Addis Ababa, the government is taking steps to address important urban issues such as improved land-use and transportation planning, the development of low-income housing, expansion of wastewater collection and treatment facilities, efficiency enhancements to the water supply system, and establishment of an urban safety net (WBG, 2015).

5 Project Alternatives

In the early stages of the development of the proposed NRL project in Addis Ababa, different project alternative option has been considered from the point of view of site layouts, alternative designs, alternative processes and materials. The “no action” alternative was also considered to evaluate the scenario in the absence of the project taking place.

5.1 Site selection

The site selection process for the proposed NRL project was confined to the premises of the EPHI campus. Several Laboratory and public health research and training facilities are already present within the EPHI compound and were in use for several decades now. The EPHI campus has developed its own ten years master plan which provides for a comprehensive framework for facility planning and site utilization from 2015-2025. The campus master plan has been instrumental in identifying and justifying the site selection for the proposed new National Reference Laboratory (NRL) building in the EPHI campus. The options of selecting other locations outside the EPHI campus for the NRL was simply rendered irrelevant due to the favourable conditions the campus master plan create for efficient use of available land, skilled manpower, work flow, shared facilities, and in ensuring the bio-safety and bio-security of the NRL

5.2 Design Considerations

The design options for the proposed facility have followed laboratory design and construction experience in which international codes, references, standards and guidelines are strictly considered. Every effort was made to follow these codes and standards; however, enforcement was based on a case by case basis, after weighing the benefit against the inevitable cost implications. In all cases, however, safety was not compromised.

As a result, several design layouts will be considered during the design phase. The preferred site layout of the proposed NRL building will be consists consisted of two main blocks with a connecting section. The large block accommodates the main laboratory spaces and the second and smaller block accommodates Laboratory Offices. It will be designed such that all Laboratory spaces and Laboratory Offices will be stacked vertically. Shared Common Equipment rooms will be provided on each laboratory floor to facilitate efficient use of shared or infrequently used equipment. All Laboratory

traffic is separated from the general traffic, allowing Laboratory professionals to travel back and forth between Main laboratory spaces and Laboratory Support spaces without having to cross public areas.

Moreover, sustainable design concepts incorporated for implementation during construction and operation phases of the NRL facility includes:

- Locally available materials will be selected to reduce transportation and processing costs.
- Material that use recycled materials and generally use sustainable manufacturing processes will be given priority over those that do not.
- Save as many existing trees as practical.
- Glazing will be carefully selected to incorporate reflective films and insulating air space to reduce solar heat gain.
- Light shelves will be considered to reflect light deeper in to the buildings to reduce use of artificial lighting during the day.
- Building management Systems (BMS) will be considered to control and maximize efficiency of lighting and HVAC operation.
- Water saving plumbing fixtures such as automatic faucets and low consumption toilets and urinals will be considered.
- Rain water and grey water recycling will be considered, at least, for landscaping purposes.

5.3 The “No action” option

The “No action” option will not be preferred for several reasons. Firstly, 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. 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. Therefore, the EPHI foresee the construction and equipping of the proposed BSL-3 National Reference Laboratory complex with the objective to elevate the capacity and status of the institute to conduct specialized testing, with a focus on the diagnosis of emerging and re-emerging lethal pathogens. Hence, the construction and equipping of the proposed BSL 3 laboratory will bolster the capacity of EPHI for advanced public health researches, provision of quality referral diagnostic

services and timely detection of causative agents of epidemic disease outbreaks thus facilitating quick and effective response to public health threats.

Secondly, the proposed BSL-3 project will serve as the Centre of Excellence and Regional Reference Laboratory of the East Africa RISLNET. Accordingly, with the level of laboratory capacity to be developed by the proposed BSL-3 NRL project, EPHI will be well set to effectively support the implementation of Africa CDC's strategies and initiatives for the promotion of public health in the Horn of Africa Region. The institute will be well positioned to assume continental responsibilities and functions for the advancement of public health as host for the Africa CDC and member of the Regional and Continental Networks of African National Public Health Institutes.

Thirdly, the land use types in the EPHI campus mainly constitutes a considerable built up area mixed with open and undeveloped parts. Thus, the No-action alternative option will not have much significance in helping to preserve environmentally sensitive or aesthetically attractive plots of land within the EPHI campus. Instead, the no-project alternative will prolong the underutilization of the available land resource in the EPHI campus for designated type of land uses by the Addis Ababa City Master plan.

In summary, the "No-action" option will undermine the huge social benefits that Ethiopia and other Countries in the region can harness from the development and operationalization of the proposed BSL-3 NRL project

5.4 Technology alternative

The overall laboratory technologies, instruments, laboratory layout and operational procedures to be utilized and installed during the operational phases will also determine the impacts of the proposed project on environment and public health. Infectious sample handling, transfer and storage facilities, infectious microbial containment technologies in the BSL 3 laboratory, the lab instruments and layouts, the laboratory operational procedures as well as the waste treatment and disposal facility options to be selected for use by the proposed BSL 3 will have a direct and/or indirect influence on the environment and public health. Escape of infectious microbial organisms that endanger public health may occur due to failure of containment technologies installed, malfunctioning lab instruments, improper laboratory layouts, or due to errors committed in operational procedures. For this reason several alternatives and standards were considered to determine the design and technology selection

criteria for developing the proposed BSL 3 Laboratory. Among the alternative standard guidelines considered include the WHO Laboratory Biosafety Manual (2004), OSHA Laboratory Safety Guidance and the World Bank EHS guidelines. Considering the nature of the proposed BSL-3 laboratory, the international standard guidelines of WHO and the World Bank EHS guidelines were preferred to guide the design, layout and selection of appropriate technologies for the proposed BSL-3 laboratory. Key elements of the design and layout principle criteria extracted from these international guidelines to be applied during the design of the proposed laboratory are included in section 2.4.

The type of medical waste treatment and disposal facilities, its operational efficiency as well as easiness for use and maintenance will also influence the occurrence of negative impacts on the environment and public health. As a result, the development of the proposed BSL 3 laboratory have considered various available technology options and make choices that guarantee high level efficiency and biosafety in waste treatment and disposal operations. The selection of high efficiency waste treatment and disposal technologies for the waste generated by the BSL 3 laboratory was conducted by a committee of highly skilled and experienced specialists and the following alternatives were considered.

The Sanitary landfill alternative: Sanitary landfills, if properly constructed and operated, could provide a relatively safe disposal method for municipal solid waste including healthcare wastes. This method, however, requires a larger space for compaction of each day's waste and there is no readily available sanitary land fill in Addis Ababa city that can receive and safely dispose healthcare wastes. Hence, this option was not selected.

The Waste Incineration alternative: Incinerators, if operated properly, eliminate pathogens from the waste and reduce waste to ashes. However, certain types of healthcare waste e.g. pharmaceutical waste or chemical waste require higher temperatures for complete destruction. Higher operating temperatures and cleaning of exhaust gases limit the atmospheric pollution and odors produced by the incineration process. This option is a preferred alternative because of the many additional advantages of incinerators in safely disposing healthcare wastes including from BSL 3 Labs. However, the incinerators to be installed at EPHI need to fill the minimum emission standard specified in the preceding section which is based on the World Bank Group EHS guideline.

As the existing incinerators do not fulfil the emission requirements of the World Bank EHS guideline, they will be removed from site following manufacturer's recommendations and procedures. Hence, the following options were considered. First, transportation of the decontaminated waste from the BSL3 lab wastes to an existing national centralized waste facility located 90 Km away from Addis Ababa. Nevertheless, this option is risky and expensive in the context of Ethiopia. The second option is on-site treatment using pyrolysis incinerator with a capacity to burn 50 kg per hour with emission reduction device control (Fabric filter coated with catalyst) made from PTFE, with parallel dedusting, lower contamination of filter dusts because of PCDD/PCDF destruction at the catalytic surface that have high efficiency reduction of dioxin upto <0.1 ng TEQ/m³. The second option is the preferred option at this stage. However, since this project will finance the design (and feasibility study) of the BSL3 lab during project implementation, the current ESIA will be updated (together with the relevant ESMP) before works are contracted (or commence) (See annex 7 for specification). The existing incinerators will be rendered obsolete, removed from site and disposed following manufacturer recommendations and procedures before BSL 3 NRL complex becomes operational.

Wastewater (Effluent) Management Alternatives: Use of a public sewer line is one of the options considered for treating and disposing liquid waste generated from the proposed BSL 3 lab at the municipal main or trunk sewer. This involves the construction of system to connect the municipal sewer line and it is inexpensive. However, this alternative is not possible currently because there is no municipal main or trunk sewer to which an EPHI sewer system could be connected. The proposed NRL project will develop its own septic tank at EPHI to dispose its own sewage, and although the existing septic tank has limited capacity, it would also use the existing septic tank. Septic tanks would be constructed according to US EPA or international standard and monitored to avoid ground water pollution. Reference would be made to standards for effluent discharge into public sewers specified in preceding section which is based on the World Bank Group EHS guideline (summarized in table 9). The detail of the design is described in section **2.6 Liquid waste management plan for EPHI's BSL 3 NRL complex.**

6 Stakeholders and Community Consultation

During data collection stage, public consultation was conducted on January 22, 2019 at the Ethiopian Public Health Institute meeting hall with participants drawn from elders, representatives of religious institution and with members of the different sector offices from woreda 09 in Gulele Sub City; and also, participants from the EPHI. The objective of the public consultation was to solicit the views and opinions of the participants towards the construction of the BSL 3 laboratory. A total of 22 people attended the public consultation and 15 of the participants were from the woreda sector offices and representatives of elders and religious institutions; and the other 7 participants were from the Ethiopian Public Health Institute.

During the consultation, the participants were briefed on the objectives and purposes of the BSL 3 laboratory by the Director of National Laboratory Capacity Building Directorate (MoH) and by the Project coordinator. It was stated that the construction of the BSL 3 laboratory, when developed, will be the biggest laboratory in the country and is envisaged to provide its service to other African countries as well. It will contribute in providing high level laboratory service and is expected to resolve and reduce issues that are related to both public health and existing social problems associated with it. That is, when it becomes operational in the future, the number of samples that are sent abroad for advanced laboratory tests is expected to reduce drastically and hence the burden of patients to access the services of such facilities will be increased there by resolving the social burden.

During the discussion, participants of the consultation meeting raised a number of issues concerning the development of the proposed BSL 3 Laboratory. The consultation was conducted in local language and the main issues raised are annexed as annex 1. The main positive and negative issues and opinions aired by the participants are summarized as follows.

- The participant stated their agreement that the proposed laboratory will enable diagnosing some chronic and critical health problems and diseases that affect mothers and children in particular. Thus construction of the laboratory is expected to contribute in providing high level medical service and the community is highly positive about its construction and is waiting anxiously. They urged to speed up all the studies that will allow the starting of the construction of the laboratory on planned time without wasting time.

- The project is expected to create employment opportunity to the local unemployed youth during its construction phase. In its operation phase the laboratory will also employ highly skilled and trained professionals and is expected to adopt new and improved technologies.
- Many participants of the community consultation aired their concerns about the effects of solid and liquid waste release and disposal. The participants stated that with regard to disposing waste materials during construction and operation phase, they advised to dispose both solid and liquid waste without affecting the community in the neighbourhood and the environment by applying recognized standard methods.
- Participants of the consultation meeting also expressed their concern on the impact of the construction activities on traffic flow in their neighbourhood by blocking roads. Participants from the community advised that, during construction work, the contractor should avoid storing construction materials, parking of construction machineries and trucks on vehicular and pedestrian walkways.
- Participants of the community consultation also raised their concern on the growing impact of high-rise tower buildings glass reflection effects on members of community in Addis Ababa City. The participants requested to ensure that installation of glasses on windows and other parts of the building do not have negative impact on the community and environment. The glasses to be installed should be as per the standard of the country, if it exists.
- Participants also stated that during the construction phase of the laboratory, the main contractor and his sub-contractors should follow national laws and regulations in the employment of construction workers, ensuring labour standards on occupational health and safety, on time settling of payments and etc. to avoid inconveniences to be created by workers mishandling. Applying such measures will allow the contractor and his sub-contractors to have peaceful working environment.

Moreover, after preparation of the draft ESIA report, the stakeholder consultation process was conducted on February 28, 2019 at the Ethiopian Public Health Institute meeting hall with participants coming from the previous participant organization, institute, religious and community representative as well as members of the different sector offices from woreda 09 in Gulele Sub City; and also

participants from the EPHI. The objective of the public consultation was to solicit the views and opinions of the participants towards the prepared ESIA report for construction of the BSL 3 laboratory at EPHI. A total of 16 people attended the public consultation and the participants were from the woreda sector offices and representatives of elders and religious institutions; and from the Ethiopian Public Health Institute.

During the consultation, the participants were briefed on the objectives and purposes of the ESIA report for BSL 3 laboratory by the Ethiopian Public Health Institute, Director of National Laboratory Capacity Building Directorate, and followed that by the Project coordinator made a presentation on the ESIA report in details. It was stated that the ESIA document this working document for construction of the BSL 3 laboratory and all activities will be done according to the ESIA document, and all related risks or impact due to the project will be mitigated based on the ESIA as well as any grievance will be also resolved accordingly. Moreover, detail presentation was done on the expected impacts and proposed mitigation for the impacts identified. After presentation, participants acknowledged the preparation of the ESIA report and they raised issues concerning on the implementation of the ESIA and they are summarized as follows.

- The participant of the community consultation recommended that during the construction the contractor should be monitored to whether the contractors adhere the proposed mitigation and ensuring occupational safety and health.
- Participants meeting also recommended that during the operation phase of the laboratory EPHI/MOH, should implement the proposed mitigation accordingly and monitor periodically for effectiveness of the proposed mitigation.
- Participants also stated that waste should be treated and disposed according to the proposed plan and mitigation measures.
- Participants also stated that during the construction the contractor should be monitored whether the contractors adhere the proposed mitigation and ensuring occupational safety and health.

Lastly the following action point are proposed to address the concerns of the community and stakeholder and they agreed on the action points.

- EPHI/MOH will establish mechanisms that will allow woreda sector offices to carry out follow up and monitoring of the project activities (discussion will made after the project approved by WB for arrangement)
- EPHI/MOH will ensure that the contractor carries out the construction works as per the rules, regulations and standards of the Environmental Protection Agency.
- EPHI/MOH will ensure that the NRL BSL 3 laboratory perform the laboratory works as per the standard BSL 3 laboratory procedure and waste management procedures (CDC & WHO manuals)
- Ensure that the contractor follows occupational, health and safety standards; and labour regulations in employment of his workforce.

Finally, the woreda administration representative and the sector offices under the woreda jurisdiction are willing to provide all required assistance and work with EPHI and MOH for successful implementation of this project.

Furthermore, additional the stakeholder consultation workshop has been conducted on May 2, 2019 at the Ethiopian Public Health Institute meeting hall with representatives coming from the Woreda 9 government admirations such as health office, tourism and culture office, civil servant offices, Environmental and climate change office, youth and children office and community elders, in addition EPHI concerned departments attended the consultation workshop and a total of 13 representatives were attended the public consultation. The objective of the public consultation was to discuss on ESIA and ICWMP focusing on proposed waste management and other mitigation measure operation of the BSL 3 NRL complex and also during construction phase.

During the consultation, the participants were briefed on the impact and mitigation measure to be taken during the implementation of the project of BSL 3 laboratory by the Ethiopian Public Health Institute, Director of National Laboratory Capacity Building Directorate, and project officer made a presentation on the types of waste generated from BSL 3 NRL, the methods for waste collection, handling, storage, transportation, treatment and disposal, including the wastewater treatment and incineration of waste techniques that proposed during the project implementation. Moreover, he has highlighted the risks associated with waste management and the proposed mitigation measure during

the project implementation. After presentation, participants acknowledged the preparation and they asked some concerns and their recommendation as follow:

- The participants of the community consultation raised their concerns about the effectiveness of the technology of incinerator.
- Participants meeting also recommended that during the operation phase of the BSL 3 laboratory EPHI/MOH, should implement the proposed technology of incinerator and liquid waste treatment plan.
- Participants also stated that there should be a monitoring system for waste treatment and disposal.

Finally, participants agreed on the importance of the project and the proposed waste management system for the BSL 3 NRL complex and the woreda administration representative and the sector offices under the woreda jurisdiction are willing to work with EPHI and MOH for effectiveness of the BSL 3 laboratory function (See minutes 3 attached in annex 1).



Figure 15: Picture that Showing the Community and stakeholder Consultation Meeting (second round)

In order to address the public concerns the following BSL 3 NRL complex design consideration have been taken into account as follows:

- The BSL3 laboratory would have design and safety requirements consist of an **anteroom** and laboratory rooms and it would have gas-impermeable walls, ceilings and floors. Air gaps under doors would be acceptable for directional airflow. If door gaps are sealed, the laboratory would not leak gaseous decontamination materials.
- The BSL3 laboratory would be designed for ease of maintenance, so that access to critical mechanical equipment (ventilation ducts, fans, piping, etc.) is outside containment. The laboratory would consist of high-quality room construction with special consideration given to joints, finishes and penetrations.
- There would be a room for large equipment decontamination. The room would be capable of being sealed for decontamination with gaseous paraformaldehyde and would have a connection to the HVAC exhaust system. All shutoffs (steam, water, natural gas) would be external to containment.
- All tall and/or heavy fixtures and equipment (e.g. BSC, autoclaves, freezers, incubators, etc.) would be fitted with a seismic anchoring system/device engineered to withstand earthquake stresses equal to 7.0 on the Richter scale.
- Work surfaces, floors, walls and ceilings would be designed, constructed and finished to facilitate easy cleaning and decontamination. The laboratory would be located away from public areas and corridors used by laboratory personnel who do not work in the BSL-3 laboratory. The BSL3 would pass third-party inspection and tests to verify that design and operational parameters have been met. Specific design, safety and operation requirements for the lab are described in in section “**2.4 Design Requirement of the proposed BSL 3 Laboratory and operation Specifications**”

The concerns of the participants among other include about effect of design, solid and liquid waste handling and disposal, impact of the construction activities and operation phase on community, and the implementation of proposed mitigation for the impacts identified and monitoring system. The approach for addressing the concerns of the community and stake holders was clearly presented (See Annex 1 minute 2 and 3 for consultation) and all concerns are including the impact mitigation and ESMP for addressing. The final ESIA has been publicly disclosed on 20 June 2019.

7 Environmental and Social Impacts and Mitigation Measures for the BSL3 NRL Complex

7.1 Potential Impacts of the Project and Proposed Mitigation Measures

In this chapter, identification, prediction and analyses of potential positive and negative impacts of construction and operation of the proposed BSL 3 NRL complex that include BSL 2 laboratories, PTPC, Biobank centre, Central Warehouse and a Laboratory Medical Equipment Maintenance Centre (LEMC) in EPHI is presented. Since the proposed site for the project is within an already established institute, most of the social and environmental impacts associated with the project will be direct in nature and mostly result from construction and operations activities. Impact analysis involved determination of magnitude, extent, duration and significance of potential impacts. A detailed assessment of impacts is presented in sections below. In the construction activity of the project impacts will be typical of any building construction works and the operation phase the complex will be related with laboratories services, the following are potential impacts related to the construction and operation activities.

7.2 Construction-phase impacts

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.

7.2.1 Positive impacts during construction phase

Generation of income to material/ equipment suppliers and contractors

Development of the project will entail civil works requiring materials such as gravel, bricks, lumber and cement. In addition, the construction materials to be procured locally, the development of the national laboratory will require supplies from abroad. Considering that the procurement of goods and services necessary for the project implementation phases, this impact has local and regional spatial extent. It is a positive but short-term impact.

Enhancement measure: Where possible the construction contractor will be advised through contractual means to maximize the application and use of locally produced construction material supplies. This will increase the quantity of materials to be procured from the various local suppliers and hence it will enhance the income generation capacity of local suppliers. On the other hand earth materials needed for construction, for example, aggregate (stones and sand) are obtained from quarry

operations. However, Conscious or unwitting purchase of these materials from unlicensed operations indirectly promotes environmental degradation at illegal quarry sites and can cause medium- to long-term negative impacts. Therefore, there will be contractual obligation for contractors to procure construction materials from quarries legitimately licensed by Government.

Employment, Gender and Labor Influx

Construction of the proposed project will create skilled and unskilled job opportunities for both men and women. It is estimated that the proposed project will create about 100 unskilled and semi-skilled temporary jobs during construction phases and about 50 skilled permanent jobs during operation. This would be a **positive** impact lasting through the construction and operation phases respectively. Owing to the moderate size of the proposed BSL 3 NRL project G+6 building (a type of building widely constructed in Addis Ababa city) it is anticipated that it will not become a mega attraction causing labour influx into the city.

Women could work in different activities in the construction and operation works of the proposed project in different capacities. It is recommended that both the construction contractor and EPHI should give priority for women in the employment of skilled and casual labourers. By giving priority to women workers the project will contribute to reduce the dependency of women on men and encourages women to learn new skills.

Enhancement measure: Wherever feasible, local people from Addis Ababa City will be considered for job opportunities commensurate with their level of skills.

7.2.2 Negative Impacts during Construction Phase

During demolition and construction of the proposed laboratory, impact may occur to environment, workers and community. According to WBG EHS Guidelines for Construction and Decommissioning the impacts are categorized by thematic groups, in to three major aspects (environment, OHS and community health and safety). Environmental impact includes noise and vibration, air pollution, solid waste and liquid waste generation. Occupational safety of workers can be impacted while workers engage in the project activity such as over-exertion, slips and falls, work at heights, hot works (welding) and electrocution, being struck by objects, injury by moving machinery and dust from construction activities. Community health impacts are related to injuries from construction activities, disease transmission and traffic accident for people in or near buildings under construction.

7.2.2.1 Impacts on Ecological Resources and Biodiversity

The EPHI BSL3 National reference laboratory Building will be constructed at existing EPHI compound and hence will have reduced impact on threatened or endangered species habitat or buffer areas. A small portion of vegetation and trees would be removed under foundation footings and other parts of the building’s base.

Extent of this impact could have temporary effects to vegetation and trees in the immediate site location area. However, these minor effects would not be long term. The intensity of the impact will be very *low* given that soil microflora would be disturbed but only for the duration of soil-intrusive activity. The sensitivity of the receptors is rated *low*. Hence significance of the impact is *low*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low 1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.2.2.2 Mitigation strategies for impact on ecological resources and biodiversity

- Limit extent of vegetation and tree clearing
- Replant and re vegetation clearing/Re-vegetating areas promptly

7.2.2.3 Impact on Geology/Soils

Except for the temporary disturbance of up to a depth of a few feet on parts of one-quarter acre of land during site preparation and construction, there would be a very minor/negligible effect upon geology, soils, or seismicity.

Extent of this impact could have temporary very minor effects on sensitive geology, soils, or seismicity. The intensity of the impact will be very *low* given that soil microflora would be disturbed

but only for the duration of soil-intrusive activity. The sensitivity of the receptors is rated *low*. Hence significance of the impact is *minor*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low 1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.2.2.4 Mitigation strategies for impact on Geology/Soils

- Soil erosion prevention measures would be in place during the construction phase to minimize erosion from storm water;
- Dust suppression measures would be employed to minimize wind erosion.

7.2.2.5 Impact due to improper construction and demolition waste management

The incremental increase in waste materials produced during this phase of work would be minimal with respect to the waste production of the entire EPHI facility. Construction debris primarily comprised of wood, metal, asphalt, paper and plastic would be the typical waste expected to be generated during construction of the BSL-3 National Reference laboratory building and tearing up of associated parking area. This solid waste would probably be disposed at the Addis Ababa landfill area. Additionally, the project could generate very minor amounts of excess uncontaminated soil from excavation activities. The soil could be stockpiled at an approved soil material management area for future use or disposal.

Demolishing of the existing building and construction activities will result in generation of waste comprising brick and concrete rubble, metal, timber, glass cullet, paper/cement bags, empty paint and solvent containers, among others. Some of the waste materials such as paints, cement, adhesives and cleaning solvents contain hazardous substances, while some of the waste materials including metal cuttings and plastic containers are not biodegradable and can have *long-term* and *cumulative* effects on the environment. Other wastes which will be generated by non-construction activities because of

the presence of the workers at the site include food debris, contaminated water from washing, cleaning equipment, construction tools and vehicles.

Inappropriate disposal of construction waste or spoil could have medium or long-term environmental and public health impact. Extent of this impact will be local to areas where waste is dumped or their immediate neighbourhoods. The intensity of the impact will be **low** given that the institute already has a waste collection system in place and dumping area. The sensitivity of the receptors is rated **low**. Hence significance of the impact is **minor**.

This waste will be managed in collaboration with Addis Ababa solid waste management municipality. Non-reusable and recyclable wastes will be disposed of to land fill and other wastes such as bricks, pieces of metals and wood will be recycled and reused.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low 1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.2.2.6 Mitigation strategies for impact due to construction and demolition waste management

- The contractor will segregate and separate the wastes properly to encourage recycling of some useful waste materials.
- Hazardous wastes will not be mixed with other solid waste generated and will be managed by way of incineration or land-filling.
- Waste will be collected from the site at least once in 24 hours and when temporarily kept on site it will be covered to minimize nuisance odour and vermin.
- The contractor and EPHI administration will work together to facilitate proper waste handling and disposal from the site. All wastes must be taken to the approved dumpsites.

In addition, the proposed project will adhere to the application of salient practices from the WBG EHS Guidelines for Construction and Decommissioning. These provide specific guidance on prevention and control of community health and safety impacts that may occur during new project development or due to expansion or modification of existing facilities.

7.2.2.7 Impacts on the health and safety of construction workers' and community health

Human health effects during site preparation and construction for the proposed BSL-3 laboratory would be the same as construction project. The effects would be much localized and would affect only site workers or visitors to the site. There would be no public human health effects. However, construction activities have the potential for exposing workers or site visitors to a number of common hazards including, for example:

- Physical hazards (slips-trips-falls, walking-working surfaces, powered hand-tool operation, pinch-points, hoisting, motor-vehicle operation, excavations, ladders, noise, heat stress, cold stress, sunburn, dust, and particulates).
- Electrical hazards (temporary electrical drops, excavations in areas with underground utilities, heavy equipment lifting with nearby overhead utilities);
- Fire and explosion hazards (portable gasoline containers for generators and other gasoline-powered equipment, fuel transfers for onsite heavy equipment operation);
- Biological hazards rare hazards (e.g., snake bites, and insect stings);

EPHI will adopt Occupational Safety and Health Administration (OSHA) regulations to reduce these hazards. Construction workers would be actively involved in potentially hazardous activities such as heavy equipment operations, soil excavations, and the handling and assembly of various building materials. Construction activities would take several months to complete. Appropriate personal protection measures would be a routine part of the construction activities (such as gloves, hard hats, steel toed boots, eye shields, and ear plugs or covers). The following would be the potential for exposing workers or site visitors to a number of common hazards and mitigation strategies.

7.2.2.8 Physical Hazards

Likely OHS risks during construction of the proposed laboratory include over-exertion, slips and falls, work at heights, hot works (welding) and electrocution, being struck by objects, injury by moving machinery and dust from construction activities. Construction activities have potential to pose occupational risks some of which could be life-threatening, for example, fatal falls if workers do not

use safety latches when working at heights. Working with high voltage and hot works (welding) pose a risk of electrocution. In addition, falling debris could injure workers if personal protective equipment (PPE) are not provided or properly used. Back injury could occur if workers lift heavy objects using inappropriate body posture. Other potential hazards might be: inadequate lighting during the night working hours or limited level of visibility during rainstorms creating difficulty for staff driving heavy equipment, driving equipment with improper brake system, lack of concentration while working and exposure to hazardous wastes such as paints, cement, adhesives and cleaning solvents. Duration of the impact will be *short-term* occurring only during the construction phase. Extent of the impact will be *local* on origin of construction workers. Ethiopia Occupational Safety and Health Directive and WB Guidelines require that workers exposed to control the emission of dangerous levels of physical forms of energy such as radiation, heat, noise, vibration and light, which are likely to be harmful and dangerous to health at workplaces.

The likelihood of the impact occurring will be high considering the usually low level of safety at construction sites in Ethiopia. Intensity of the impact will be *medium* given that some accidents could be minor and not life threatening while others can be grave leading to permanent disability or loss of life of construction workers. Sensitivity of the receptor is *medium* resulting in moderate impact significance.

Impact significance

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.2.2.9 Mitigation Strategies for Physical Hazards

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

- All construction workers will be oriented on safe work practices and guidelines and ensure that they adhere to them. The workers will also receive tool box talks/ briefings when workers

move to new activities. In addition, new workers will be provided with inductions on health and safety features and procedures.

- Training will be conducted on how to prevent and manage incidences. This will involve proper handling of electricity, water etc. and on various modes of escape, conduct and responsibility during such incidences. All workers will fully be aware and mentally prepared for potential emergency.
- Regular drills shall be carried 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 in case of incidences.
- Use signage to warn staff and/ or visitors that are not involved in the construction activities of dangerous places.
- Strict instructions shall be given for drivers of heavy equipment.
- Supervision of works shall be done regularly to ensure that safety conditions are met while any deviation from safety regulations is immediately reclaimed following the best practices of safety at work procedures.
- Communication will be ensured in between workers and drivers of heavy equipment.
- Develop evacuation procedures to handle emergency situations.
- Provide adequate OHS protective gear to construction workers, such as
- Hearing protection for workers doing in places over 80 Decibels for 8 hours
- Safety Glasses/Face Shield for those working with any chemical or using any mechanical equipment to protect their eyes and face
- For Hand, Use correct gloves for the job
- For Body, use body overall to protect against dust, vapours, splashes
- Safety shoe such as Water/Chemical/ electrical hazard Resistant Boots for foot Protection.

7.2.2.10 Electrical and Explosive Hazards

Ethiopian Public Health Institute has sufficient electric power supply from Ethiopian Electric Power and portable gasoline containers for generators and construction equipment and other gasoline-powered equipment, fuel transfers for onsite heavy equipment operation. Most of the construction equipment use gasoline so that they would be gasoline containers risk of explosive. The contractor would make available gasoline for daily base consumptions in order to avoid explosive. The

contractor would employ lightning protection designed to meet the requirements. All Equipment need electric power, without provisions for electrical safety, there is a risk of electric hazard in the site. Exposed or faulty electrical devices, such as circuit breakers, panels, cables, cords and hand tools, can pose a serious risk to workers. The contractor also has technician that oversee and provide maintenance for any electric malfunctioning.

Duration of the impact would be *long-term* lasting entire life of laboratory operation phase, local in spatial extent affecting onsite facilities, patients, lab workers and neighbouring communities with possibly irreversible impact. The likelihood of the impact occurring, and its intensity are *low* if “facility design” is standard laboratory design. However, *sensitivity* on the receptors will be *medium*, thereby giving moderate impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.2.2.11 Mitigation strategies for Electrical and Explosive Hazards

WBG EHS Guideline and WHO Laboratory Biosafety Manual 3rd edition recommends actions include:

- It is essential that all electrical installations and equipment are inspected and tested regularly, including earthing/grounding systems. Circuit-breakers and earth-fault-interrupters should be installed in appropriate laboratory electrical circuits. Circuit-breakers do not protect people; they are intended to protect wiring from being overloaded with electrical current and hence to prevent fires. Earth-fault interrupters are intended to protect people from electric shock.
- All laboratory electrical equipment would be earthed/grounded, preferably through three-prong plugs.
- All laboratory electrical equipment and wiring would conform to national electrical safety standards and codes

- Disconnect equipment attached to high-voltage or high-amperage power sources from the source or provide a lockout device on the breaker box to prevent circuit activation before maintenance is performed.
- Because electrical devices can generate sparks, do not use them near flammable or volatile gases or liquids.
- Never place flammable liquids in a household refrigerator. The spark generated by the door-activated light switch can ignite fumes trapped in the unit, causing an explosion and fire.
- Specialized refrigerators would be used when storing chemicals that have explosion potential.
- Gasoline would be placed away from fire.

7.2.2.12 Traffic accident impacts

Construction activities may result in a significant increase in number of vehicles during transport of construction materials and equipment, which will lead to increasing risk of traffic-related accidents or injuries to workers and EPHI community. But traffic movement in EPHI will have separate route from other internal activities of EPHI staff. The traffic accident will be minimal, and the duration of the impact will be *short-term* occurring only during the construction phase. The *sensitivity* of receptors is *high* given that some accidents would lead to permanent damage and others loss of life while *the intensity* of the impact is *low* given the relatively small incremental increase of the traffic volume caused by the construction activities. Therefore, significance of the impact is *moderate*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.2.2.13 Mitigation strategies for traffic accident impacts

The project will adhere to the application of salient practices from the WBG EHS Guidelines for Community Health and Safety in section of Traffic Safety as follow:

- Contractors will adopt best transport safety practices with the goal of preventing traffic accidents and minimizing injuries suffered by project personnel and the public.
- Contractors will emphasize safety among all drivers. Specifically, they will ensure drivers respect speed limits through trading Centres and areas with public institutions;
- Safe traffic control measures will be used, including flag persons to warn of dangerous conditions.
- Project Management will require contractors to regularly maintain vehicles to minimize potentially serious accidents such as those caused by brake failure commonly associated with loaded construction trucks.
- Clear warning signs will be placed around the construction premise and emphasize (provide) personal protective gears to persons in the area.

7.2.2.14 Impact on Air Quality

During site preparation and construction, the use of heavy equipment would generate combustive-engine exhausts that would contribute to air pollution. However, since there would be very few of these pieces of equipment and their use would be limited in time, the potential effect on ambient air quality would be temporary and localized. During construction there would be a temporary increase in particulate emissions. Operation of construction vehicles such as dump trucks, cranes, and those involved in waste disposal actions would also produce temporary and localized emissions of other air pollutants. Mobile sources, such as construction and waste transport vehicles, would produce other air pollutants (such as sulphur oxide), but the quantities would be minimal relative to the number of mobile sources required.

Traffic-borne emissions include dust and exhaust fumes. The trucks used to transport various building materials from their sources to the project site generate emissions of SO₂, CO₂, CO, NO_x and particulates. Demolition of the existing built environment will lead to considerable levels of indoor cement dust which can affect workers and patients. Deteriorated indoor air quality would be of critical effect to especially asthmatic construction workers, patients and laboratory workers with either minor or severe health impact depending on level and duration of exposure.

The EPHI is located close to the main highway which is relatively high traffic road that give rise to gaseous emissions and dust. However, the emission from vehicle will not contribute for the

deterioration of air quality as compared to high traffic movement in the area. The demolition activities that may take place during re-modification will make the impact *intensity* to be *medium* when control measures are not instituted and the *sensitivity* on the receptors will be *medium* resulting in a *moderate* impact significance.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.2.2.15 Mitigation strategies for impact on air quality

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

- Contractors should use dust screens or nets in windows, doorways and ventilators of rooms where demolition or other dusty construction activities are occurring.
- Ensure good housekeeping and clean construction operations where, among other necessary actions, dust should be quickly swept off cement floors and collected in covered containers.
- Safety officer at the facility should have authority to inspect and restrain contractors from generating excessive dust within healthcare buildings.
- Trucks shall be covered during haulage of construction materials and should be diverted away from busy areas of the institute;
- Construction work should be undertaken by an experienced and duly registered contractor with a verifiable sense of environmental awareness and responsibility.
- Workers will be provided with PPE and the use of PPE shall be enforced.

7.2.2.16 Impact of Noise and Vibration

It is possible that noise levels would exceed at least for periods of several minutes at a time o working 8-hour 75-dBA threshold limit value, but only during daylight hours and only in the immediate vicinity of the site preparation and construction activity. Members of the public would not be exposed

during the daytime or night-time to noise levels exceeding city planning (ambient noise level greater than 75 dBA beyond the boundaries of the site, nor greater than 60 dBA at the boundary of a residential district). This is predicated on the distance of the proposed facility being about 400 m to the nearest residence.

Heavy equipment such as front-end loaders and backhoes would produce intermittent noise levels at around 73 to 94 dBA at 15 m from the work site under normal working conditions (Cantor 1996). Construction truck traffic would occur frequently but would generally produce noise levels below that of the heavy equipment. The finishing work within the building structures would create noise levels slightly above normal background levels for office work areas. Noise levels may go up to around 80 dBA at the work site if light machinery is used in this stage of construction (Cantor 1996). Workers would be required to have hearing protection if site-specific work produced noise levels above the EPHI action level of 80 dBA for steady-state noise. Sound levels would be expected to dissipate to background levels well short of the EPHI compound. The additional construction-worker personal vehicular traffic would not be expected to increase the present noise level produced by vehicular traffic Swaziland Street; this Street is a major thoroughfare with multiple lanes of traffic going in both directions and a roundabout on the southwest corner of the EPHI campus.

During construction activities, 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. Considerable levels of noise and vibrations will mainly result from use of heavy construction equipment. Relatively high noise levels are also expected in the area during demolition phase.

Ethiopia has no national legislation for noise, but World Bank guidelines have been adopted by EPA and are used for benchmarking purposes along with the draft National Noise Standards that are being prepared. The guidelines being adopted by EPA for Ethiopia for daytime perimeter noise is 55 decibels (DBA). Table 16 provides the provisional noise standards being adopted by WB guidelines values.

Table 16: Limit Values for Noise level (Source: World Bank, 2012)

Area Code	Category of Area	Limits in DBA	
		Day time ¹	Night time ²
A	Industrial area	75	70
B	Commercial area	65	55

C	Residential area	55	45
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Note

- 1 Day time reckoned to be between 6.00 am to 9.00pm
- 2 Night time reckoned to be between 9.00pm to 6.00am

Construction noise and vibration from manual or motorized demolition activities could affect patients and health workers in the EPHI. Though the level of discomfort caused by noise is subjective, the most commonly reported impacts of increased noise levels are interference in oral communication (Stansfeld and Matheson, 2003) and disturbance to some vibration sensitive laboratories equipment housed in EPHI. Impact receptors include staff, patients and their attendants. The impact *intensity* will be *medium and short term* if an experienced contractor is contracted to carry out the construction activities. However, *sensitivity* on receptors will be *medium*, hence a *moderate* impact significance.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.2.2.17 Mitigation strategies for impact due to noise and vibration

The following action will be the mitigation strategies:

- Contractor will be careful when selecting equipment to avoid use of old or damaged machinery with high level of noise emissions that would have a negative impact in the environment.
- Contractor will ensure that equipment is properly serviced and efficient.
- Contractors will cordon off construction equipment units with noise absorbing materials, for example, plywood rather than iron sheets.
- Construction workers will be aware of the sensitive nature of workplaces they are operating in and advised to limit verbal noise or other forms of noise. For example, metallic objects or tools can be passed on to a colleague rather than dropping or throwing them with loud bangs.

- The contractor will ensure that noise levels emanating from machinery, vehicles and noisy construction activities are kept at a minimum for the safety, health and protection of people in the nearby buildings.
- Noise and vibration will be minimized at the project site and surrounding areas through sensitization of construction truck drivers to switch off vehicle engines while offloading materials.
- All generators and heavy-duty equipment will be insulated or placed in enclosures to minimize disrupting ambient noise levels.

Moreover, the project will adhere to the application of salient practices from the WBG EHS Guidelines for Construction and Decommissioning. These provide specific guidance on prevention and control of noise and vibrations recommended noise and vibration reduction and control strategies includes:

- 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 should be avoided.
- Using noise control devices, such as temporary noise barriers and exhaust muffling devices for combustion engines. Noise due to construction machineries should be minimized by introducing silencer to the construction machineries
- Avoiding or minimizing project transportation through community areas

7.2.2.18 Impact on social service through disruption of laboratory/ sample collection services

Since laboratory services will continue to be provided during the construction period, patients seeking to give or deliver samples to the present sample collection rooms found next to the site will be urged to cross through the construction area. Frequent changes of designated safe pathways across the construction site to the sample collection area will entail moving patients. This may cause inconveniences and temporary disruption in delivery of sample collection services to patients.



Figure 16: Sample collection Building near the laboratory

Temporary rearrangement of service areas can affect services delivery. The impact *intensity* will be *low* given that another entrance gate will be arranged. The *sensitivity* on the receptors will be *low* given that it might involve rearrangement of sample collection site resulting into congestion. This results into *minor* impact significance.

Impact significance

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.2.2.19 Mitigation strategies for impact on social service through disruption of laboratory/ sample collection services

The following action will be the mitigation strategies

- Plan pre-construction activities early to identify suitable rooms or adjoining buildings into which patients or service areas can be relocated with minimal inconvenience, especially to sample collection laboratory to be re-modified.
- Contractors will work closely and harmoniously with the institute administration to find practical ways to minimize social cost of temporary disruption of services.

In addition to this, the project will adhere to the application of salient practices from the WBG EHS Guidelines for Structural Safety of Project Infrastructure. These provide specific guidance on prevention and control of community health and safety impacts that may occur during new project development or due to expansion or modification of existing facilities. By thematic categories, they address the OHS and community health and safety below.

Structural Safety of Project Infrastructure

Hazards posed to the public while accessing project facilities may include:

- Physical trauma associated with failure of building structures
- Burns and smoke inhalation from fires
- Injuries suffered because of falls or contact with heavy equipment
- Respiratory distress from dust, fumes, or noxious odours
- Exposure to hazardous materials

Reduction of potential hazards is best accomplished during the design phase when the structural design, layout and site modifications can be adapted more easily. The following issues will be considered and incorporated as appropriate into the planning, siting, and design phases of a project:

- Inclusion of buffer strips or other methods of physical separation around project sites to protect the public from major hazards associated with hazardous materials incidents or process failure, as well as nuisance issues related to noise, odours, or other emission
- Incorporation of siting and safety engineering criteria to prevent failures due to natural risks posed by earthquakes, tsunamis, wind, flooding, landslides and fire. To this end, all

7.2.2.20 Analysis of Abnormal Events and Accident Scenarios

The site preparation and construction part of deals with routine injury and illness related to non-residential building construction. Routine accidents are those that commonly occur on construction sites (for example, slips, trips and falls). Because they are routine, they are not considered abnormal

events, nor do they take into consideration accidents with more substantial consequences, such as those resulting from catastrophic events. The Proposed Action facility has the potential to be affected by earth movements due to earthquakes. The earthquake could cause damage to the proposed one-story building during construction and could injure construction workers by physical mass-movement. However, no hazardous materials or pathogens would be present during construction, and therefore no exposures to these materials would result to workers or the public from a seismic event. There is no report on earthquakes, so the probability is very low.

7.2.2.21 Emergency Preparedness and Response during construction

An emergency is an unplanned event when a project operation loses control, or could lose control, of a situation that may result in risks to human health, property, or the environment, either within the facility or in the local community. Emergencies do not normally include safe work practices for frequent upsets or events that are covered by occupational health and safety. The BSL 3 NRL projects would have an Emergency Preparedness and Response Plan that is commensurate with the risks of the facility and that includes the following basic elements:

Administration (policy, purpose, distribution, definitions, etc.)

- Organization of emergency areas (command Centres, medical stations, etc)
- Roles and responsibilities
- Communication systems
- Emergency response procedures
- Emergency resources
- Training and updating
- Checklists (role and action list and equipment checklist) to be prepared during project commenced
- Business Continuity and Contingency
- Additional information is provided for key components of the emergency plan, as follows below.

7.2.2.21.1 Communication Systems

Worker notification and communication

Alarm bells, visual alarms, or other forms of communication would be used to reliably alert workers to an emergency. Related measures include:

- Testing warning systems at least annually (fire alarms monthly), and more frequently if required by local regulations, equipment, or other consideration
- Installing a back-up system for communications on-site with off-site resources, such as fire departments, if normal communication methods may be inoperable during an emergency.

7.2.2.21.2 Community Notification

If a local community may be at risk from a potential emergency arising at the facility, the contractor would implement communication measures to alert the community, such as:

- Audible alarms, such as fire bells or sirens
- Fan out telephone call lists
- Vehicle mounted speakers
- Communicating details of the nature of the emergency
- Communicating protection options (evacuation, quarantine)
- Providing advice on selecting an appropriate protection option

Emergency information would be communicated to the media through:

- A trained, local spokesperson able to interact with relevant stakeholders, and offer guidance to the contractor for speaking to the media, government, and other agencies
- Written press releases with accurate information, appropriate level of detail for the emergency, and for which accuracy can be guaranteed

7.2.2.21.3 Fire Services

- The contractor would consider the level of local firefighting capacity and whether equipment is available for use at the facility in the event of a major emergency or natural disaster.
- If insufficient capacity is available, firefighting capacity would be acquired that may include pumps, water supplies, trucks, and training for personnel.

7.2.2.21.4 Medical Services

- The contractor would provide first aid attendants for the facility as well as medical equipment suitable for the personnel, type of operation, and the degree of treatment likely to be required prior to transportation to hospital.

7.2.2.21.5 Availability of Resources

Appropriate measures for managing the availability of resources in case of an emergency include:

- Maintaining a list of external equipment, personnel, facilities, funding, expert knowledge, and materials that may be required to respond to emergencies. The list would include personnel with specialized expertise for spill clean-up, flood control, engineering, water treatment, environmental science, etc., or any of the functions required to adequately respond to the identified emergency
- Providing personnel who can readily call up resources, as required
- Tracking and managing the costs associated with emergency resources
- Considering the quantity, response time, capability, limitations, and cost of these resources, for both site-specific emergencies, and community or regional emergencies
- Considering if external resources are unable to provide sufficient capacity during a regional emergency and whether additional resources may need to be maintained on-site

7.2.2.21.6 Mutual Aid

- Mutual aid agreements decrease administrative confusion and provide a clear basis for response by mutual aid providers.
- Where appropriate, mutual aid agreements would be maintained with other organizations to allow for sharing of personnel and specialized equipment.

7.2.2.21.7 Contact List

- The contractor would develop a list of contact information for all internal and external resources and personnel. The list would include the name, description, location, and contact details (telephone, email) for each of the resources, and be maintained annually.

7.2.2.21.8 Training and Updating

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

Programs would:

- Identify training needs based on the roles and responsibilities, capabilities and requirements of personnel in an emergency

- Develop a training plan to address needs, particularly for firefighting, spill response, and evacuation
- Conduct annual training, at least, and perhaps more frequent training when the response includes specialized equipment, procedures, or hazards, or when otherwise mandated
- Provide training exercises to allow personnel the opportunity to test emergency preparedness, including:
 - Desk top exercises with only a few personnel, where the contact lists are tested and the facilities and communication assessed
 - Response exercises, typically involving drills that allow for testing of equipment and logistics
 - Debrief upon completion of a training exercise to assess what worked well and what aspects require improvement
 - Update the plan, as required, after each exercise. Elements of the plan subject to significant change (such as contact lists) would be replaced
 - Record training activities and the outcomes of the training

7.2.2.21.9 Business Continuity and Contingency

Measures to address business continuity and contingency include:

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

7.3 Operation Phase

7.3.1 Positive Impact during Operation Phase

Improved medical surveillance services

The project will positively impact the health sector of Ethiopia and the African region through easing access to diagnostic services for public health emergency diseases and other communicable diseases.

It will help to enhance access to advanced diagnostic services for vulnerable groups; improve capacity

to provide referral diagnostic services; and strengthen laboratory-based disease surveillance to provide early warning of public health emergency.

Enhancement measures: Appropriate staffing with technical/ medical personnel adequately trained in use of newly installed equipment.

Employment opportunities: Operation of the BSL 3 NRL laboratory will create additional permanent technical and non-technical job opportunities for laboratory and other supportive professionals, cleaners, etc. for both men and women.

Enhancement measure: Wherever feasible, local qualified people will be considered for job opportunities. EPHI should give priority for women in the employment of skilled and casual labourers. By giving priority to women workers the project will contribute to reduce the dependency of women on men and encourages women to learn new skills. Adequate occupational health and safety standards should be provided to ensure the work environment is conducive.

7.3.2 Negative Impact during Operation Phase

7.3.2.1 Impacts on Ecological Resources and Biodiversity

The operation of the proposed BSL-3 lab would have little effects on biodiversity. Infectious microorganisms handled in the proposed BSL3 lab might be introduced into the environment under two conditions. The first is the disposal of sanitary wastewater to Addis Ababa Kality Waste Water Treatment Plant (as described in ICWMP). The disposal would only be done after treated at proposed BSL 3 septic tank. Sanitary waste passing through the wastewater treatment plant undergoes several stages of treatment that would inactivate any microbes that survived the initial disinfectant treatment at the BSL-3 facility. The second is relates to emergency preparedness and response activities. There is a possibility for infectious microorganisms to be introduced into the environment if they are not contained within the laboratory due to accidents / emergencies e.g. a fire response or natural phenomena event. However, even if they should escape containment, several environmental factors should effectively kill microorganisms in the vegetative state. They include ultraviolet light, dehydration, high temperatures, freezing temperatures, and the presence of free oxygen. The survival or death curves indicate that microbial populations die off quickly (DA 1989). Extent of this impact could have long effects to wildlife species in the immediate site location area. The intensity of the impact will be *low* given that soil microflora would be disturbed but only for the duration of soil-

intrusive activity. The sensitivity of the receptors is rated *low*. Hence significance of the impact is *low*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low 1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.2.2 Mitigation strategies for impact on ecological resources and biodiversity

- Personnel working on the BSL 3 NRL complex would be trained on emergency preparedness and responses as well as in handling of infectious materials and waste management during accidents / emergencies.

7.3.2.3 Impacts on Geology/Soils

There would be no effect from the proposed BSL-3 NRL facility operation on geology, soils, or seismicity. Soils surfaces not covered by the building footprint or not paved would be landscaped to control erosion from storm water runoff.

7.3.2.4 Occupational Health and Safety and Community Health Concerns

The type and rate of injuries and illnesses expected during operation of the proposed BSL-3 laboratory would be the same as the other BSL 3 laboratory and existing biological research laboratories operated by EPHI. While the most obvious potential concern of operating a BSL-3 laboratory involves handling of infectious organisms (listed in the Annex 4), the proposed facility would have attributes of most laboratories in that it would have identified physical, electrical, and chemical hazards.

The proposed laboratory would not use radioactive materials, propellants, or high explosive materials, and the quantities of hazardous chemicals stored in the facility at any one time would be just a few litres each of chemical disinfectants (such as sodium hypochlorite or potassium hypochlorite) and biologic stabilizers (phenol). Chemicals such as paraformaldehyde would not be stored in the facility

but brought in only when required for fumigation (the facility has a minimal amount of storage space). The hazardous chemicals used and stored would be tracked using chemical inventory system and handled according to Material Safety Data Sheet (MSDS) and EPHI Safety Manual.

The potential for injuries and illnesses involving routine laboratory operations presents a greater health risk to workers than does the potential for injury and illnesses associated with handling infectious substances at the proposed BSL 3 laboratory would handle highly infectious agents list annexed (Annex 4). 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-3 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. There would be no discernible public human health effect from routine BSL-3 laboratory operations at the proposed facility. There has been an extremely low incidence of laboratory-acquired infections associated with operations in EPHI laboratories since EPHI. Specifically, a recent bibliographic database (Collins 2000) based on reports starting from about the beginning of the 20th century and continuing up through August 2000 reveals substantial reductions in laboratory-acquired infections reported in the 1990s.

Surveillance of laboratory acquired infection (LAI) is, therefore, an efficient marker to evaluate the effectiveness of biosafety and to optimize the risk assessment in BSL 3 laboratories. Before the era of containment laboratories, the 10 microorganisms responsible for >50% of LAI were brucellosis, Q fever, viral hepatitis, typhoid fever, tularemia, tuberculosis, dermatomycoses, Venezuelan equine encephalitis, psittacosis, and coccidioidomycosis. It was reported that 85% of LAI were caused by *Mycobacterium tuberculosis*, *Coxiellaburnetii*, hantaviruses, arboviruses, hepatitis B and C viruses, *Brucella* spp., *Salmonella* spp., *Shigella* spp., and *Cryptosporidium* spp. (Byers and Harding 2006). In the USA, from 2004 to 2010, only 11 LAIs were reported to CDC for microorganisms listed as Biological Select Agents and Toxins, 6 cases due to *Brucella* spp., four cases due to *Francisellatularensis*, and one case due to *Coccidioidesimmitis/ posadasii*. Although there is no harmonized system for the reporting of laboratory incidents and accidents at the EU level, few LAIs have been described in European laboratories during the last decade highlighting a drastic reduction of these accidents in CL3 laboratories. Doubtless, current practices have also minimized worker's

pathogen exposition and improvements in containment equipment, engineering controls, and safety training contributed greatly to this reduction (Pastorino et al. 2017).

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 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 (Pastorino et al. 2017).

EPHI Experience in biological research and diagnostic laboratories has been for several decades of years. Based on information provided by the EPHI National Laboratory Capacity Building director and Laboratory accreditation and Quality Improvement team, EPHI has operated BSL-1- and BSL-2 equivalent laboratories at least for the last 50 years without any infections associated with their activities. Also, there were no unintentional releases of infectious agents to the environment or to the public associated with the EPHI's biological research and diagnostic laboratories. In addition, EPHI also operates mobile BSL 3 laboratory for the last 3 years, and EPHI has a biosafety and biosecurity team working on biosafety and biosecurity issues throughout the country to strengthen the biosafety and biosecurity system at large. However, the following potential impacts are anticipated to occur, and the associated mitigations measures are also planned of the constrictions.

Additionally, there was that there have been no incidences of laboratory-acquired infections recorded for EPHI workers. Based on extensive experience with the safe handling of biological materials at EPHI, it is projected that the diagnosis and scientific research to be conducted at the proposed BSL-3 facility would not result in significant impacts from normal operations to workers or the public as well as to the environment. Anecdotal reporting of human health issues elsewhere at BSL-3 or similar laboratories have indicated that while laboratory-acquired or laboratory-associated infections

(specifically, the “all other” category of nonfatal injury and illness rates reported by the BLS) do occur, they should be considered abnormal events due to their infrequency of occurrence. There are several reasons that routine BSL-3 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).

7.3.3 Impact of escaping of Infectious Agents from BSL-3 Containment

In the BSL 3 laboratory there would be highly infectious agents in storage, diagnosis process or culture. So, that there would be a possibility to escape infectious agents BSL-3 Containment. Potential means for infectious agents to leave the BSL-3 containment 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-3 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-3 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-3 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 fibre 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 fibres but uses several physical properties of air movement around fibres to capture the particles.

Since in BSL 3 laboratory highly infectious agents are escaped from BSL-3 Containment, it may have potential risks resulting life-threatening for personnel working in BSL 3 laboratory and community. The agents that may cause severe human disease, present a serious 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 EPHI facility would always wear PPE while working in BSL-3. The institute would also benefit from a long term practices and experience in performing similar procedures in the existing mobile BSL 3 laboratory through its established system. However, *sensitivity* on the receptors will be *high*, thereby giving *moderate* impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.4 Mitigation strategies for risk of escaping of infectious agents from BSL-3 containment

The following mitigation strategies would be implemented to prevent infectious agents from escaping BSL-3 Containment

- Laboratory personnel working in BSL 3 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
- HEPA filters at the EPHI BSL-3 facility (including those in the BSCs) would be tested annually and replaced as necessary.

Additionally, the potential impact would further be reduced through the following intervention:

- Effective vaccines or therapeutic measures would be available for all risk groups
- The use of pest control programs would limit the potential for transmission of infectious agents from animals to humans.
- 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.

7.3.5 Impact of escaping of Infectious Agents from BSL 2 labs, PTPC and biobank centres

In the PTPC and biobank would be infectious agents in storage, PT diagnosis process or culture. So, that there would be a possibility to escape infectious agents from PTPC and biobank. Potential means for infectious agents to leave the PTPC and biobank 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, the detail information described above for BSL 3 lab.

Since in PTPC and biobank infectious agents are escaped from facilities, it may have fewer potential risks resulting life-threatening for personnel working in PTPC and biobank and community. The agents that may cause less severe human disease, present a serious 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 EPHI facility would always wear PPE while working in PTPC and biobank facilities. The institute would also benefit from a long-term practices and experience in performing similar procedures in the existing mobile BSL 3 laboratory through its established system. However, *sensitivity* on the receptors will be *medium*, thereby giving *moderate* impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.6 Mitigation strategies for risk of escaping of infectious agents from PTPC and biobank facilities

The following mitigation strategies would be implemented to prevent infectious agents from escaping from PTPC and biobank facilities

- Personnel working in PTPC and biobank 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.
- Workers would be trained in equipment operating and handling techniques during operation,
- Equipment would be periodically maintained and calibrated according to manufacture recommendation
- 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.
- PTPC and biobank would be locked always and access restricted for non-authorized personnel
- All agents would be contained within the laboratory and biosecurity system would be in place.

7.3.7 Potential Occupational Health and safety impacts associated with BSL 3 Laboratory operation

Operating the proposed BSL3 lab involves handling of infectious organisms. However, there has been extremely low incidence of laboratory-acquired infections associated with operations in CDC-registered laboratories since the implementation of CDC-developed guidelines issued in 1974. Though the most obvious potential concern of operating a BSL-3 laboratory involves handling of infectious organisms), the proposed lab would have attributes of most laboratories in that it would have identified physical, electrical, and chemical hazards. This BSL3 laboratory would not use radioactive materials, propellants, or high explosive materials, and the quantities of hazardous chemicals stored in the lab at any one time would be just a few litres each of chemical disinfectants (such as sodium hypochlorite or potassium hypochlorite) and biologic stabilizers (phenol). Chemicals

such as paraformaldehyde would not be stored in the lab but brought in only when required for fumigation (the facility has a minimal amount of storage space). The hazardous chemicals used and stored will be tracked using computerized chemical inventory system) and handled according to international good practices.

There would be no apparent public human health effect from routine BSL-3 laboratory operations at the proposed EPHI BSL3 laboratory. There are several reasons that routine BSL-3 laboratory or similar laboratory operations do not normally produce infectious disease-related health effects to workers, their families, or the general public. The combination of utilizing the guidelines, standards, practices and procedures established by the CDC, NIH, WHO together with BSL-3 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. The potential for injuries and illnesses involving routine laboratory operations presents a greater health risk to workers than does the potential for injury and illnesses associated with handling infectious substances. However, there are different potential means for infectious agents to leave the BSL-3 containment 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.

The EPHI BSL3 lab will be designed to severely limit the potential for possible vector-borne transmission through insects and rodents. The use of pest control programs would limit the potential for transmission of infectious agents from animals to humans. The primary concern for vehicle-borne transmission would be by the workers' clothing or skin and hair, as all other materials leaving the BSL-3 must go through a sterilization by autoclave or chemical disinfection. EPHI will adopt the guidelines established by the CDC and NIH, which would be followed within the proposed BSL-3 lab, 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. HEPA filters at the EPHI BSL-3 lab (including those in the BSCs) would be tested annually and replaced as necessary.

Regardless of the presence or failure of HEPA filters, many environmental factors effectively and naturally kill airborne microbes in their vegetative state. These factors include ultraviolet light, dehydration, high temperatures, freezing temperatures, and the presence of free oxygen. Together these factors account for a substantial reduction in the number of microorganisms. While outdoors,

the sun, temperature, and other atmospheric conditions ensure that microbial populations die off quickly, generally within minutes. Mathematical predictions of the potential survival of microorganisms in the environment estimate that only about 0.01 percent can resist the chemical or physical inactivation found in the outside environment.

It is a well-known fact that, Primary hazards to personnel working in Biosafety Level 3 is related with indigenous or exotic agents which are highly infectious microorganism (*Ethiopian selected agents and toxins are listed in annex 4*), 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 (e.g., blending, vortexing, and sonication), pouring/decanting and spilling/splashing of culture 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. In relation to this, containment and good laboratory practices would be implemented in the BSL-3 laboratory facility at EPHI as to reduce such kind of risks. On top of this, more emphasis would be placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to potentially infectious aerosols.

Workers in BSL 3 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 would be accessible in each of the BSL-3 laboratories where these chemicals are to be used. Some chemicals adversely affect the health of those who handle them or inhale their vapours. Apart from overt poisons, several 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. EPHI will assign designated personnel (safety officer) who would regularly follow the appropriateness of chemical utilization, chemical incompatibility during storage and the overall chemical safety practice.

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. In such regards, appropriate work processes, engineering, and administrative controls would be in place at EPHI BSL-3 laboratory facility to avoid or minimize release of biological agents into the environment.

Since BSL 3 laboratory is a place where highly infectious agents are handled and manipulated, it may have potential risks resulting life-threatening for personnel working in BSL 3 laboratory and community. The agents that may cause severe human disease, present a serious hazard to workers, and may present a risk of spreading to the community. Duration of the impact would be *long-term* lasting for the entire life of the affected person or short-term depending on the hazard exposed to. However, *sensitivity* on the receptors will be *high*, thereby giving *moderate* impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.8 Mitigation Strategies for Potential Occupational Health and safety impacts associated with BSL 3 Laboratory operation

At EPHI, the BSL-3 laboratory will be constructed in compliance with the “facility design” as proposed in WHO & WBG EHS Guidelines. Additionally, PPE would be effectively used. Consequently, the intensity of impact that would associate with BSL-3 laboratory operation will be expected to be low.

Apart from the above mentioned strategies the following measures will be implemented to mitigate the potential risks associated with BSL 3 laboratory operation at EPHI.

- Laboratory personnel working in BSL 3 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.
- All procedures involving the manipulation of infectious materials would be conducted within BSCs or other physical containment devices and a BSL-3 laboratory will have special engineering and design features.

In addition, the following standard and special safety practices, equipment, and facility requirements would apply to BSL-3 laboratory facility at EPHI. These standard 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 (BMBL) 5th Edition as follow:

Best practices for the proposed BSL3 laboratory

- All persons entering the laboratory would be advised of the potential hazards and meet specific entry/exit requirements.
- Laboratory personnel would be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory.
- A laboratory-specific biosafety manual will be prepared and adopted as policy. The biosafety manual will be available and accessible.
- The laboratory supervisor would ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-3 agents.
- Potentially infectious materials would 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 would be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
- Equipment would be decontaminated before repair, maintenance, or removal from the laboratory.
- Incidents that may result in exposure to infectious materials would be immediately evaluated and treated according to procedures described in the laboratory biosafety manual. All such

incidents would 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 would be conducted within a BSC, or other physical containment devices.
- Persons would wash- their hands after working with potentially hazardous materials and before leaving the laboratory.
- Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption would not be permitted in laboratory areas. Food would be stored outside the laboratory area.

Safety Equipment (Primary Barriers and PPE) for the proposed BSL3 Laboratory

- All procedures involving the manipulation of infectious materials would be conducted within a BSC in Class II or Class III,
- Workers in the laboratory would wear protective laboratory clothing with a solid-front, such as tie-back or wrap-around gowns, scrub suits, or coveralls. Protective clothing will not be worn outside of the laboratory.
- Reusable clothing would be decontaminated before being laundered. Clothing is changed when contaminated.
- Eye and face protection (goggles, mask, face shield or other splash guard) would be used for anticipated splashes or sprays of infectious or other hazardous materials. Eye and face protection would be disposed of with another contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses in laboratories would also wear eye protection.
- Gloves would be worn to protect hands from exposure to hazardous materials. Gloves would not be worn outside the laboratory. Dispose of used gloves with another contaminated laboratory waste. Hand washing protocols would be rigorously followed.
- Personal protective equipment and clothing, and equipment selection would be based on the nature of the work performed in the laboratory.
- Protective clothing would be worn when working in the BLS 3 laboratory. However, it would be removed before leaving the laboratory, and hands would be washed.

- Either a fully buttoned laboratory coats, gowns, coveralls, or a long-sleeved, back opening gowns or coveralls would be used in BSL-3 laboratory at EPHI. Aprons may also be worn over laboratory coats or gowns where necessary to give further protection
- Goggles, safety spectacles, face shields would be used to protect the eyes and face from splashes and impacting objects will depend on the activity performed.
- Respiratory protection would be used when carrying out high-hazard procedures. The choice of respirator will depend on the type of hazard(s) and it be available with interchangeable filters for protection against gases, vapors, particulates and microorganisms.
- Gloves would be used during handling and performing laboratory procedures. Disposable microbiologically approved latex, vinyl or nitrile surgical-type gloves would be used widely for general laboratory work, and for handling infectious agents and blood and body fluids.

Laboratory Facilities (Secondary Barriers) for the proposed BSL3 laboratory

The BSL 3 laboratory doors would be self-closing and have locks in accordance with the institutional policies. The laboratory would be separated from areas that are open to unrestricted traffic flow within the building. Additionally, laboratory access would be restricted. Access to the laboratory is through two self-closing doors. A clothing change room (anteroom) may be included in the passageway between the two self-closing doors (See annex 7 for detail information).

7.3.9 Potential impacts associated with operation of BSL 2 laboratories, PTPC and biobank

Operating the proposed BSL 2 laboratories, PTPC and biobank involves handling of infectious organisms. However, there has been extremely low incidence of laboratory-acquired infections associated with operations in CDC-registered laboratories since the implementation of CDC-developed guidelines issued in 1974. Though the most obvious potential concern of operating a PTPC and biobank involves handling of infectious organisms), the proposed PTPC and biobank would have attributes of most laboratories in that it would have identified physical, electrical, and chemical hazards. The PTPC and biobank would not use radioactive materials, propellants, or high explosive materials, and the quantities of hazardous chemicals stored in the lab at any one time would be just a few litres each of chemical disinfectants (such as sodium hypochlorite or potassium hypochlorite) and biologic stabilizers (phenol). Chemicals such as paraformaldehyde would not be stored in the lab but brought in only when required for fumigation (the facility has a minimal amount of storage space).

The hazardous chemicals used and stored will be tracked using computerized chemical inventory system) and handled according to international good practices.

There would be no apparent public human health effect from routine BSL-2 laboratory, PTPC and biobank facility complex. There are several reasons that routine BSL 2 laboratories, PTPC and biobank or similar laboratory operations do not normally produce infectious disease-related health effects to workers, their families, or the general public. The combination of utilizing the guidelines, standards, practices and procedures established by the CDC, NIH, WHO 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. The potential for injuries and illnesses involving routine laboratory operations presents a greater health risk to workers than does the potential for injury and illnesses associated with handling infectious substances. However, there are different potential means for infectious agents to leave the BSL-2 labs, PTPC and biobank facility 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.

The EPHI BSL 3 NRL building complex would be designed to severely limit the potential for possible vector-borne transmission through insects and rodents. The use of pest control programs would limit the potential for transmission of infectious agents from animals to humans. The primary concern for vehicle-borne transmission would be by the workers' clothing or skin and hair, as all other materials leaving the building would go through a sterilization by autoclave or chemical disinfection. EPHI will adopt the guidelines established by the CDC and NIH, which would be followed within the proposed BSL 2 labs, PTPC and biobank facilities 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. BSCs HEPA filters at the BSL 2labs and PTPC would be tested annually and replaced as necessary.

It is a well-known fact that, Primary hazards to personnel working in PTPC and biobank is related with indigenous or exotic agents which are 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 (e.g., blending, vortexing, and sonication), pouring/decanting and spilling/splashing of culture fluids. Inoculation hazards include needlesticks 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. In relation to this, containment and good laboratory practices would be implemented in the PTPC and biobank facilities at EPHI as to reduce such kind of risks. On top of this, more emphasis would be placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to potentially infectious aerosols.

Workers in BSL 2 labs, PTPC and biobank facilities 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 would be accessible in each of the PTPC and biobank where these chemicals are to be used. Some chemicals adversely affect the health of those who handle them or inhale their vapours. 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. EPHI will assign designated personnel (safety officer) who would regularly follow the appropriateness of chemical utilization, chemical incompatibility during storage and the overall chemical safety practice.

Since BSL 2 labs, PTPC and biobank facilities are a place where infectious agents are handled and stored, it may have less potential risks resulting life-threatening for personnel working in PTPC and biobank and community as the agents handled and stored in the PTPC and biobank facilities are with less health risk. The agents that may cause human disease, present a serious hazard to workers, and may present a risk of spreading to the community. Since EPHI has an experience for several years on managing of BSL 2 laboratories, mobile BSL 3 labs and the BSL 2 laboratories, PTPC and biobank centre will be constructed in compliance with the ‘‘facility design’’ as proposed in WHO & WBG EHS Guidelines for BSL 2 laboratory. In addition to this, PPE would be effectively used. Consequently, the intensity of impact that would associate with proposed BSL 2 labs; PTPC and

biobank centre operation will be expected to be low. Duration of the impact would be *long-term* lasting for the entire life of the affected person or short-term depending on the hazard exposed. However, *sensitivity* on the receptors will be *medium*, thereby giving a *moderate* impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.10 Mitigation strategies for impacts associated with of operation BSL 2 Laboratories, PTPC and biobank

Apart from the above-mentioned strategies the following measures will be implemented to mitigate the potential risks associated with BSL 3 laboratory operation at EPHI.

- Personnel working in PTPC and biobank Centre 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.
- All procedures involving the manipulation of infectious materials would be conducted within BSCs or other physical containment devices and PTPC and biobank Centre would have special engineering and design features.

In addition, the following standard and special safety practices, equipment, and facility requirements would apply to BSL-2 laboratory facility at EPHI. These standard 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 (BMBL) 5th Edition as follow:

Best practices for the proposed BSL 2 labs, PTPC and Biobank

- All persons entering the laboratory would be advised of the potential hazards and meet specific entry/exit requirements.

- Personnel would be provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory.
- Each institution should consider the need for collection and storage of serum samples from at-risk personnel.
- A specific bio-safety manual would be prepared and adopted as policy. The biosafety manual would be available and accessible.
- The supervisor would ensure that personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.
- Potentially infectious materials would be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
- All equipment would be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.
 - Spills involving infectious materials would be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
 - Equipment would be decontaminated before repair, maintenance, or removal from the laboratory.
- Incidents that may result in exposure to infectious materials would be immediately evaluated and treated according to procedures described in the laboratory biosafety manual. All such incidents would be reported to the laboratory supervisor. Medical evaluation, surveillance, and treatment should be provided, and appropriate records maintained.
- All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment devices.
- All persons entering the facilities would be advised of the potential hazards and meet specific entry/exit requirements.
- Equipment would be decontaminated before repair, maintenance, or removal from the laboratory.
- Incidents that may result in exposure to infectious materials would be immediately evaluated and treated according to procedures described in the laboratory biosafety manual. All such incidents would be reported to the laboratory supervisor. Medical evaluation, surveillance, and treatment would be provided, and appropriate records maintained.
- Persons would 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 would not be permitted in laboratory areas. Food would be stored outside the laboratory area.

7.3.11 Impact of handling of infectious materials and specimens in the proposed BSL 3 laboratory

As BSL 3 laboratory is expected to perform diagnosis for highly infectious agents, during specimens' collection, handling, transportation and storage, there will be a risk of exposure for the specimen. If the specimen has a highly infectious agents, it may cause severe human disease, present a serious hazard to workers, and may present a risk of spreading to the community.

Duration of the impact associated with poor handling of infectious materials would be *long-term* lasting that would affect the entire life of the affected person or short-term depending on the type of hazards exposed to. The intensity of the impact would be *low* when the specimen management is undertaken as per WHO & WBG EHS Guideline and if the workers use PPE during specimen handling, as well as the institute practices and experience in handling specimens in similar existing mobile BSL 3 laboratory. However, *sensitivity* on the receptors will be *high*, thereby giving *moderate* impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.12 Mitigation strategies for risk associated with handling of infectious materials and specimens in the proposed BSL 3 laboratory

The following strategies would be implemented to mitigate the potential risks associated with BSL 3 laboratory regarding specimen handling.

- Specimen containers would be robust and would not leak when the cap or stopper is correctly applied. No material would remain on the outside of the container. Containers would be correctly labelled to facilitate identification. Specimen request or specification forms would not be wrapped around the containers but placed in separate, preferably waterproof envelopes.
- To avoid accidental leakage or spillage, secondary containers, such as boxes, would be used, fitted with racks so that the specimen containers remain upright. The secondary containers may be of metal or plastic, would be autoclavable or resistant to the action of chemical disinfectants, and the seal would preferably have a gasket. They would be regularly decontaminated. Laboratories that receive large numbers of specimens would designate a room or area for this purpose.

Moreover, regarding the collection, labelling and transport of specimens the following will also be considered:

- Standard precautions would always be followed; gloves would be worn for all procedures.
- Blood would be collected from patients by trained staff.
- For phlebotomies, conventional needle and syringe systems would be replaced by single-use safety vacuum devices that allow the collection of blood directly into stoppered transport and/or culture tubes, automatically disabling the needle after use.
- The tubes would be placed in adequate containers for transport to the laboratory and within the laboratory facility.
- Request forms would be placed in separate waterproof bags or envelopes.
- Reception staff would not open these bags.

Opening packages: personnel who receive and unpack specimens would be aware of the potential health hazards involved, and would be trained to adopt standard precautions, particularly when dealing with broken or leaking containers. Primary specimen containers would be opened in a biological safety cabinet. Disinfectants would be available.

Avoiding the dispersal of infectious materials: To avoid the premature shedding of their loads, microbiological transfer loops would have a diameter of 2–3 mm and be completely closed. The shanks would not be more than 6 cm in length to minimize vibration. Working areas would be decontaminated with a suitable disinfectant at the end of each work period.

Avoiding ingestion of infectious materials and contact with skin and eyes: Large particles and droplets (> 5 µm in diameter) released during microorganism manipulations settle rapidly on bench surfaces and on the hands of the operator. Disposable gloves would be worn. Laboratory workers would avoid touching their mouth, eyes and face. Food and drink would not be consumed or stored in the laboratory. The face, eyes and mouth would be shielded or otherwise protected during any operation that may result in the splashing of potentially infectious materials.

Avoiding injection of infectious materials: Accidental inoculation resulting from injury with broken or chipped glassware would be avoided through careful practices and procedures. Glassware would be replaced with plastic ware whenever possible. Accidental injection may also result from sharps injuries and workers at the BSL-3 facility in EPHI would implement the following when possible:

- Needle-stick injuries can be reduced by: (a) minimizing the use of syringes and needles (e.g. simple devices are available for opening septum-stoppered bottles so that pipettes can be used instead of syringes and needles; or (b) using engineered sharp safety devices when syringes and needles are necessary.
- Needles would never be recapped. Disposable articles would be discarded into puncture-proof/puncture-resistant containers fitted with covers.

Opening of ampoules containing lyophilized infectious materials: Care would be taken when ampoules of freeze-dried materials are opened, as the contents may be under reduced pressure and the sudden inrush of air may disperse some of the materials into the atmosphere. Ampoules would always be opened in a biological safety cabinet. The following procedures would be implemented while opening ampoules.

- First the outer surface of the ampoule would be decontaminated.
- A file mark would be made on the tube near to the middle of the cotton or cellulose plug, when present.
- The ampoule would be held in alcohol-soaked cotton to protect hands before breaking it at a file scratch.
- The top would be removed gently and treated as contaminated material.
- The plug would be removed with sterile forceps when it is still above the contents of the ampoule.
- Liquid would be added for resuspension slowly to the ampoule to avoid frothing.

Storage of ampoules containing infectious materials: Ampoules containing infectious materials would never be immersed in liquid nitrogen because cracked or imperfectly sealed ampoules may break or explode on removal. If very low temperatures are required, ampoules would be stored only in the gaseous phase above the liquid nitrogen. Otherwise, infectious materials would be stored in mechanical deep-freeze cabinets or on dry ice. Laboratory workers would wear eye and hand protection when removing ampoules from cold storage. The outer surfaces of ampoules stored in these ways would be disinfected when the ampoules are removed from storage.

Standard precautions with blood and other body fluids, tissues and excreta: Standard precautions (which include “universal precautions”) would be designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection.

Opening specimen tubes and sampling contents: Specimen tubes would be opened in a biological safety cabinet.

- Gloves would be worn. Eye and mucous membrane protection would also be used (goggles or face shields).
- Protective clothing would be supplemented with a plastic apron.
- The stopper would be grasped through a piece of paper or gauze to prevent splashing.

7.3.13 Risk associated with handling and storage of infectious materials and specimens in the proposed BSL 2 laboratories, PTPC and Biobank

As discussed in the above the impact of the handling of infectious materials and specimens in BSL 3 lab, the risk of in BSL 2 lab, PTPC and biobank are almost similarly but the impact would be different. Since BSL 2 labs, PTPC and Biobank centre are expected to hand and store infectious agents, during specimens’ collection, handling, transportation and storage, there will be a risk of exposure for the specimen. If the specimen has an infectious agent, it may cause human disease, present a hazard to workers, and may present a risk of spreading to the community.

Duration of the impact associated with poor handling and storage of infectious materials would be *long-term* lasting that would affect the entire life of the affected person or short-term depending on the type of hazards exposed to. The intensity of the impact would be *low* when the specimen management is undertaken as per WHO & WBG EHS Guideline and if the workers use PPE during specimen handling, as well as the institute practices and experience in handling specimens in similar

existing mobile BSL 3 laboratory. However, *sensitivity* on the receptors will be *medium*, thereby giving *moderate impact significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low 1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.14 Mitigation strategies for risk associated with handling of infectious materials and specimens in the proposed PTPC and Biobank centre

The detail mitigation strategies for risk associated with handling and storage of infectious materials and specimens is described in detail in above for BSL 3 laboratories, in addition to that, the following strategies would be implemented to mitigate the potential risks associated with BSL 2 labs, PTPC and Biobank Centre regarding specimen handling and storage.

- Specimen containers would be robust and would not leak when the cap or stopper is correctly applied. No material would remain on the outside of the container. Containers would be correctly labelled to facilitate identification. Specimen request or specification forms would not be wrapped around the containers but placed in separate, preferably waterproof envelopes.
- To avoid accidental leakage or spillage, secondary containers, such as boxes, would be used, fitted with racks so that the specimen containers remain upright. The secondary containers may be of metal or plastic, would be autoclavable or resistant to the action of chemical disinfectants, and the seal would preferably have a gasket. They would be regularly decontaminated. Laboratories that receive large numbers of specimens would designate a room or area for this purpose.
- **Storage of ampoules containing infectious materials:** Ampoules containing infectious materials would never be immersed in liquid nitrogen because cracked or imperfectly sealed ampoules may break or explode on removal. If very low temperatures are required, ampoules would be stored only in the gaseous phase above the liquid nitrogen. Otherwise, infectious

materials would be stored in mechanical deep-freeze cabinets or on dry ice. Laboratory workers would wear eye and hand protection when removing ampoules from cold storage. The outer surfaces of ampoules stored in these ways would be disinfected when the ampoules are removed from storage.

7.3.15 Impact of improper use of equipment in the BSL 3 laboratory

Laboratory workers are at risk for repetitive use of laboratory equipment such as pipetting, centrifuge, BSC homogenizers, shakers, blenders, sonicators, freezers, autoclave and other equipment. Certain items of equipment may create hazards when they are used, and the common hazards related to laboratory equipment are Aerosols, splashing and tube breakage rotors and impaired ultrasonic hearing, dermatitis, burning, splash and spillage. In addition, due to improper use equipment-related accidents might occur.

Duration of the impact would be *long-term* lasting for the entire life of laboratory operation phase, local in spatial extent affecting onsite facilities’ lab workers with possibly impact. The likelihood of the impact occurring, and its intensity are *low* when the laboratory complies with laboratory standards and good laboratory practices. However, *sensitivity* on the receptors will be *medium*, thereby giving moderate impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.16 Mitigation strategies for risk associated with the use of equipment in the BSL 3 laboratory

EPHI would implement the following mitigation measures:

- Training of workers in equipment operating and handling techniques during operation.
- Periodic maintenance and calibration of equipment according to manufacture recommendation.

- Operation of equipment according to the manufacturer's instructions.

In addition, the following measures would be taken from WHO laboratory biosafety manual and WBG EHS Guideline would be implemented for the prevention and control of risks emanating from equipment utilization in BSL-3 laboratory:

Safety during use of biological safety cabinets (BSC)

The use and limitations of biological safety cabinets would be explained to all potential users, with reference to national standards and relevant literature. Written protocols or safety or operations manuals would be issued to staff. It would be made clear that the cabinet will not protect the operator from spillage, breakage or poor technique.

- The cabinet would not be used unless it is working properly.
- The glass viewing panel would not be opened when the cabinet is in use.
- Apparatus and materials in the cabinet would be kept to a minimum. Air circulation at the rear plenum would not be blocked.
- Bunsen burners would not be used in the cabinet. The heat produced will distort the airflow and may damage the filters.
- All work would be carried out in the middle or rear part of the working surface and be visible through the viewing panel.
- Traffic behind the operator would be minimized.
- The operator would not disturb the airflow by repeated removal and reintroduction of his or her arms.
- Air grills would not be blocked with notes, pipettes or other materials, as this will disrupt the airflow causing potential contamination of the material and exposure of the operator.
- The surface of the biological safety cabinet would be wiped using an appropriate disinfectant after work is completed and at the end of the day.
- The cabinet fan would be run for at least 5 min before beginning work and after completion of work in the cabinet.
- Paperwork would never be placed inside biological safety cabinets.

Safety during use of pipettes and pipetting aids

- A pipetting aid would always be used. Pipetting by mouth would be prohibited.

- All pipettes would have cotton plugs to reduce contamination of pipetting devices.
- Air would never be blown through liquid containing infectious agents.
- Infectious materials would not be mixed by alternate suction and expulsion through a pipette.
- Liquids would not be forcibly expelled from pipettes.
- Contaminated pipettes would be completely submerged in a suitable disinfectant contained in an unbreakable container. They would be left in the disinfectant for the appropriate length of time before disposal.
- A discard container for pipettes would be placed within the biological safety cabinet, not outside it.
- Syringes fitted with hypodermic needles would not be used for pipetting.
- Devices for opening septum-capped bottles that allow pipettes to be used and avoid the use of hypodermic needles and syringes would be used.
- To avoid dispersion of infectious material dropped from a pipette, an absorbent material would be placed on the working surface; this would be disposed of as infectious waste after use.
-

Safety during use of centrifuges

- Centrifuges would be operated according to the manufacturer's instructions.
- Centrifuges would be placed at such a level that workers can see into the bowl to place trunnions and buckets correctly.
- Tubes and specimen containers would always be securely capped for centrifugation.
- The buckets would be loaded, equilibrated, sealed and opened in a biological safety cabinet.
- Buckets and trunnions would be paired by weight and, with tubes in place, correctly balanced.
- The amount of space that would be left between the level of the fluid and the rim of the centrifuge tube would be given in manufacturer's instructions.
- Distilled water or alcohol (propanol, 70%) would be used for balancing empty buckets. Saline or hypochlorite solutions would not be used as they corrode metals.
- Sealable centrifuge buckets (safety cups) would be used for microorganisms in Risk Groups 3 and.
- When using angle-head centrifuge rotors, care would be taken to ensure that the tube is not overloaded as it might leak.

- The interior of the centrifuge bowl would be inspected daily for staining or soiling at the level of the rotor. If staining or soiling is evident then the centrifugation protocols would be re-evaluated.
- Centrifuge rotors and buckets would be inspected daily for signs of corrosion and for hair-line cracks.
- Buckets, rotors and centrifuge bowls would be decontaminated after each use.
- After use, buckets would be stored in an inverted position to drain the balancing fluid.

Infectious airborne particles may be ejected when centrifuges are used. These particles travel at speeds too high to be retained by the cabinet airflow if the centrifuge is placed in a traditional open-fronted Class I or Class II biological safety Cabinet. Enclosing centrifuges in Class III safety cabinets prevents emitted aerosols from dispersing widely. However, good centrifuge technique and securely capped tubes offer adequate protection against infectious aerosols and dispersed particles.

Safety during use homogenizers, shakers, blenders and sonicators

- Caps and cups or bottles would be in good condition and free from flaws or distortion. Caps would be well-fitting, and gaskets would be in good condition.
- Pressure builds up in the vessel during the operation of homogenizers, shakers and sonicators. Aerosols containing infectious materials may escape from between the cap and the vessel. Plastic, in particular, polytetrafluoroethylene (PTFE) vessels would preferably be used than glass. Glass may break, releasing infectious material and possibly wounding the operator.
- When in use, homogenizers, shakers and sonicators would be covered by a strong transparent plastic casing. This would be disinfected after use. Where possible, these machines would be operated, under their plastic covers, in a biological safety cabinet.
- At the end of the operation the containers would be opened in a biological safety cabinet.
- Hearing protection would be provided for people using sonicators.

Safety during use autoclaves

An autoclave is common laboratory equipment that uses high pressure steam to sterilize laboratory equipment / items. During use of autoclave, there may be hazards such as burns from steam and hot parts of the autoclave, and the following measure would be taken with the use of autoclaves:

- Autoclave would be operated according to the manufacturer's instructions and trained personnel only.
- Manual handling, when lifting items in / out of the autoclave.
- Never operate autoclaves unless you are trained and authorised to do so.
- Never autoclave flammable or toxic materials
- Personnel would wear a lab coat, goggles and heat resistant gloves, keeping your sleeves tucked into the gloves to stop steam going up your sleeves.
- Personnel would make sure the chamber pressure has returned to zero before opening the door. Stand away from the door and open it slowly to avoid a rush of steam and wait 5 minutes after opening door before removing liquids so they don't burn you.
- If there is something wrong with the autoclave, stop using it, place a sign on it to ensure others don't use it and report it immediately to your supervisor

Safety during use of refrigerators and freezers

- Refrigerators, deep-freezers and solid carbon dioxide (dry-ice) chests would be defrosted and cleaned periodically, and any ampoules, tubes, etc. that have broken during storage removed. Face protection and heavy-duty rubber gloves would be worn during cleaning. After cleaning, the inner surfaces of the cabinet would be disinfected.
- All containers stored in refrigerators, etc. would be clearly labelled with the scientific name of the contents, the date stored and the name of the individual who stored them. Unlabelled and obsolete materials would be autoclaved and discarded.
- An inventory would be maintained of the freezer's contents.
- Flammable solutions would not be stored in a refrigerator unless it is explosion proof. Notices to this effect would be placed on refrigerator doors.

7.3.17 Impact of improper use of equipment in the BSL 2 labs, PTPC and Biobank

Personnel working BSL 2 labs, PTPC and Biobank are at risk for repetitive use of equipment such as pipetting, centrifuge, BSC, homogenizers, shakers, blenders, sonicators, freezers, autoclave and other equipment. Certain items of equipment may create hazards when they are used, and the common hazards related to laboratory equipment are Aerosols, splashing and tube breakage rotors and impaired ultrasonic hearing, dermatitis, burning, splash and spillage. In addition, due to improper use equipment-related accidents might occur.

Duration of the impact would be *long-term* lasting for the entire life of laboratory operation phase, local in spatial extent affecting onsite facilities' lab workers with possibly impact. The likelihood of the impact occurring, and its intensity are *low* when the laboratory complies with laboratory standards and good laboratory practices. However, *sensitivity* on the receptors will be *medium*, thereby giving moderate impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.18 Mitigation strategies for risk associated with the use of equipment in the BSL 2 laboratory, PTPC and Biobank

The detail mitigation strategies for risk arising from the use of equipment is described in detail in the above **section**, in addition to that, the following strategies would be implemented to mitigate the potential risks associated the use of equipment

- Training of workers in equipment operating and handling techniques during operation.
- Periodic maintenance and calibration of equipment according to manufacture recommendation.
- Operation of equipment according to the manufacturer's instructions.

7.3.19 Impact of contamination of the BSL 3 laboratory, BSL 2 laboratories, PTPC and Biobank Facilities

BSL 3 laboratory perform several types of analysis for specimens collected from human, so that during the activities performed, laboratory space, furniture and equipment will be contaminated by different type of hazards materials including highly infectious agents and chemicals. In addition BSL 2 labs, PTPC and Biobank facilities also perform several type of activities such as specimen analysis, handling allocation, and storage, so that during the activities performed, working space, furniture and equipment will be contaminated by different type of hazards materials including infectious agents and

chemicals. The contamination of the laboratory facilities, furniture and equipment may result from laboratory procedures: performing and handling of culture, specimens and chemicals. If the contamination is due to highly infectious agents, it may cause severe human disease, present a serious hazard to workers, and may present a risk of spreading to the community.

Duration of the impact would be *long-term* lasting entire life of the affected person or short-term depending of the type hazard exposed to. The intensity of the impact will be *low* when “facility design” complied with what is proposed in WHO & WBG EHS Guidelines. The intensity of impact of contamination to laboratory could also be lowered through good laboratory practices and via compliance to laboratory standards. EPHI has been involved in similar activities performing similar laboratory procedures on the institute’s mobile BSL-3 laboratory. Hence, such an established system in EPHI had created experienced work force that would contribute towards reducing most of the intensity of impacts in the operation phase. However, *sensitivity* on the receptors will be *high*, thereby giving moderate impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.20 Mitigation strategies for risk of contamination of the BSL 3 laboratory

The following mitigation strategies would also be implemented:

- Workers would be trained on evacuation of the contaminated area
- Workers would also be trained on
 - Decontamination or disinfection,
 - Rinsing, and wiping dry of the spillage area with an absorbent cloth by personnel wearing adequate protective clothing and
 - Decontamination or disinfection of the protective clothing if necessary.

- Handling and managing of spill and splash
- Administration (policy, purpose, distribution, definitions, etc) and organization of emergency areas (command Centres, medical stations, etc) would be available.

In addition, the following mitigation strategies that are more detailed in WHO Laboratory Biosafety Manual 3rd edition, and CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) will also be implemented in EPHI:

Laboratory environmental decontamination

Decontamination of the laboratory space, its furniture and its equipment require a combination of liquid and gaseous disinfectants. Surfaces would be decontaminated using a solution of sodium hypochlorite (NaOCl); a solution containing 1 g/l available chlorine would also be applied for general environmental sanitation, but stronger solutions (5 g/l) would be used when dealing with high-risk situations. For environmental decontamination, formulated solutions containing 3% hydrogen peroxide (H₂O₂) would make suitable substitutes for bleach solutions. Rooms and equipment would be decontaminated by fumigation with formaldehyde gas generated by heating paraformaldehyde or boiling formalin. A specially trained will be carried out for personnel involved in the fumigation process. All openings in the room (i.e. windows, doors, etc.) would be sealed with masking tape or similar before the gas is generated. Fumigation would be conducted at an ambient temperature of at least 21 °C and a relative humidity of 70%.

After fumigation the area would be ventilated thoroughly before personnel are allowed to enter. Appropriate respirators would be worn by anyone entering the room before it has been ventilated. Gaseous ammonium bicarbonate would be used to neutralize the formaldehyde. Fumigation of smaller spaces with hydrogen peroxide vapor is also effective but requires specialized equipment to generate the vapor.

The proposed laboratory would not use radioactive materials, propellants, or high explosive materials, and the quantities of hazardous chemicals stored in the facility at any time would be just a little volume for each of chemical disinfectants (such as sodium hypochlorite or potassium hypochlorite) and biologic stabilizers (phenol). Chemicals such as paraformaldehyde would not be stored in the facility but brought in only when required for fumigation (the facility has a minimal amount of storage space). The hazardous chemicals used and stored would be tracked using chemical inventory system) and handled according to the MSDS and EPHI Safety manual.

Biological safety cabinet decontamination

To decontaminate Class I and Class II cabinets, equipment that independently generates, circulates and neutralizes formaldehyde gas is available. Alternatively, the appropriate amount of paraformaldehyde (final concentration of 0.8% paraformaldehyde in air) would be placed in a frying pan on an electric hot plate using WHO laboratory biosafety manual. Another frying pan, containing 10% more ammonium bicarbonate than paraformaldehyde, on a second hot plate would also be placed inside the cabinet. The hot plate leads would be plugged in outside the cabinet, so that operation of the pans would be controlled from the outside by plugging and unplugging the hot plates as necessary. If the relative humidity is below 70%, an open container of hot water would also be placed inside the cabinet before the front closure is sealed in place with strong tape (e.g. duct tape). Heavy gauge plastic sheeting is taped over the front opening and exhaust port to make sure that the gas cannot seep into the room. Penetration of the electric leads passing through the front closure would also be sealed with duct tape. The plate for the paraformaldehyde pan would be plugged in. It is unplugged when all the paraformaldehyde has vaporized. The cabinet would be left undisturbed for at least 6 h. The plate for the second pan would then be plugged in and the ammonium bicarbonate can vaporize. This plate would then be unplugged, and the cabinet blower would be switched on for two intervals of approximately 2 second each to allow the ammonium bicarbonate gas to circulate. The cabinet would be left undisturbed for 30 min before the front closure (or plastic sheeting) and the exhaust port sheeting would be removed. The cabinet surfaces would be wiped down to remove residues before use.

7.3.21 Potential impact during the operation of Central Warehouse

Although the quantities of hazardous chemicals stored in the facility of PTPC and biobank would be at a few chemicals, the central warehouse would be large amount. However, there would be no any radioactive substance stored at the central house as well as at EPHI level. Nearly all industries, including laboratory facilities, use chemicals in variable amounts and must therefore store them, as well as the produced chemical waste before disposal. Acting as a warehouse, the storage facility also shelters the chemicals: it protects the personnel and the environment from the effects of a spill, or an aerosol or gas emission.

Chemical emissions: Toxicological, chemical and physical properties define the hazards of a chemical. However, in a chemical storage facility further factors add on: quantity, storage form, proximity of various

chemicals, activities carried out in the facility, etc. The following example illustrates this hazard increase: hydrochloric acid and iron fillings, stored separately, are not flammable, yet when they come in contact, their reaction releases hydrogen, an extremely flammable gas, which may cause fire or explosion. But the hazard first materializes, when chemicals are spilt, e.g. out of containers. Among numerous causes for a chemical leak are:

- Mechanical damage of the container (bumped during transportation, tilted over after it was placed on an unstable ground or rack...);
- Container ageing (plastic becoming brittle with time or under the effect of light or low temperatures, plastic softening through heat, metal corrosion, interaction between the container and its filling);
- Expansion of the filling (vapour pressure build-up with heat, crystallisation at low temperature, chemical decomposition with time or induced by light exposure);
- Sampling and transfer of chemicals.

This chemical dispersion can have serious consequences for health of the staff community and environment as follow:

Damage to health: A leaked chemical, especially when it is volatile or a gas at room temperature can cause intoxication. The risk of intoxication is particularly insidious, when the spilt chemical on its own does not have any severe toxicological property but releases a toxic substance when it reacts with the environment or other chemicals stored in the same room (for instance, gaseous chlorine forms, when liquid bleach comes in contact with an acidic solution). Besides these acute effects, a wide range of chronic effects can also occur (such as impaired organ function, allergies and cancers. Contrary to acute effects, the occurrence of those chronic effects does not necessarily depend on the level of exposure: allergies, for example, can be triggered by exposure to very low concentrations of a sensitizing agent. Moreover, among all chemicals categories, liquefied gases constitute a specific hazard. Contact with liquefied gases causes severe frostbites and, even if not toxic, once released, their rapid expansion can locally reduce the oxygen concentration to dangerously low levels and therefore cause asphyxia.

Damage to the environment and facilities: Apart from the hazards they represent for workers' health, stored chemicals may induce hazards for facilities, fauna and flora, and the general public off site. When they are spilled,

chemicals can irreversibly alter soils, streams and ground waters, thus affecting surrounding communities. The nature of the environmental damage caused by a chemical spill depends on its toxicological, physical and chemical properties (form, reactivity, solubility, persistence, bioaccumulation, etc.) and those of the polluted site (permeation properties, etc.), but pollution risk increases with the amount of stored chemicals.

Stored chemicals can also cause accidental fire or explosions. account for few occupational accidents each year, however, when they happen, they often claim lives and have dramatic environmental and economic consequences. Hostile fire is an uncontrolled oxidation reaction between combustible matter and an oxidant. Large amounts of both elements can often be found in a storage facility. Oxygen is the usual oxidant involved in fire, while stored goods (organic chemicals like solvents or polymer pellets), packaging materials (plastic bags or containers) or pallets act as combustible matter. Various sources of energy can start a fire, e.g. a spark, heat, an explosion. Accidental explosions can be either “physical” or “chemical”. A physical explosion can happen when, for example, pressure builds up inside a chemical container. Chemical explosions result from chemical reactions: a decomposition (storage of explosive materials) or the inflammation of an explosive atmosphere (storage of flammable chemicals, of oxidising metal dust, etc.). In some cases, the chemical reaction is essentially combustion. Many dusts of combustible materials as diverse as flour and coal, can lead to a risk of explosion at critical concentrations in the air.

Risk associated with warehouse may result from handling of chemicals. The proposed central warehouse project operators would have procedure to prevent chemical and materials hazardous. This control measures would be designed and implemented accordingly, and the institute would continue providing training on the appropriate usage, handling and storage of chemicals and hazardous. Chemical hazards can most effectively be prevented through a hierarchical approach that including designing a chemical storage facility.

As research institute and reference laboratory, EPHI use a large amount of chemical and hazardous materials for different purposes. Professional has extensive experience in handling of chemicals and hazardous materials and takes regular training on chemical handling and storage. Chemical hazards represent potential for illness or injury due to single acute exposure or chronic repetitive exposure to toxic, corrosive, sensitizing or oxidative substances. They also represent a risk of uncontrolled

reaction, including the risk of fire and explosion, if incompatible chemicals are inadvertently mixed. However, accidents due to chemical and hazardous materials never been reported in the institution. Thus, the risk of the accidents due to chemical and hazardous materials would be low at central warehouse.

Duration of the impact would be *long-term* lasting through the entire life of the affected person or short-term depending on the hazard exposed to. The intensity of the impact is *low* if appropriate ‘‘facility design’’ is adopted and PPE used by workers. However, *sensitivity* on the receptors will be *high*, thereby giving *moderate* impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.22 Mitigation measures for potential impact during the operation of Central Warehouse

According to WBG EHS Guideline and Laboratory Biosafety Manual 3rd edition, the following mitigation strategies will be implemented:

- 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
- Where corrosive, oxidizing, or reactive chemicals are used, handled, or stored, qualified first-aid would always be ensured. Appropriately equipped first-aid stations would be easily accessible throughout the place of work, and eye-wash stations and/or emergency showers would be provided close to all workstations where the recommended first-aid response is immediate flushing with water
- Keeping the number of employees exposed, or likely to become exposed, to a minimum

- Communicating chemical hazards to workers through labelling and marking according to national and internationally recognized requirements and standards, including the International Chemical Safety Cards (ICSC), Materials Safety
- Material 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
- The procedure would be following in the event of a significant chemical spill

Besides, the OSHA recommends following these guidelines for safe chemical storage and all personnel handling the hazardous materials at warehouse as well as at the laboratory would

- Read chemical labels and MSDSs for specific storage instructions.
- Store chemicals in a well-ventilated area; however, do not store chemicals in a fume hood.
- Maintain an inventory of all chemicals in storage.
- Return chemical containers to their proper storage location after use.
- Store glass chemical containers so that they are unlikely to be broken.
- Store all hazardous chemicals below eye level.
- Never store hazardous chemicals in a public area or corridor.
- Separate acids from bases. Store these chemicals near floor level.
- Isolate perchloric acid from organic materials. Do not store perchloric acid on a wooden shelf.
- Separate highly toxic chemicals and carcinogens from all other chemicals. This storage location should have a warning label and should be locked.
- Separate acids from flammables.
- Not keep peroxide-forming chemicals longer than twelve months.
- Not allow picric acid to dry out.
- If flammables need to be chilled, store them in a laboratory-safe refrigerator, not in a standard refrigerator.
- Flammables would be stored in a flammable storage cabinet.
- Store reactive materials separate from corrosives or flammables.
- Store Nitric acid (reactive and corrosive) separately from other acids and flammables.

- Storage location would clearly indicate which group/code is stored in that location. Each shelf or cabinet should indicate the colour.
- Groups would always be separated by a vertical divider not horizontal divider. (see diagrams below)
- Each chemical container would be clearly labelled by its storage colour
- Ideally liquids would be isolated by secondary containment.

7.3.23 Impact of fire outbreak

Different combustible materials such as flammable liquids, solid materials and loose electrical connections etc could cause serious fire incidents in BSL 3 laboratory complex facility, BSL 2 laboratories, PTPC, biobank Centre, central warehouse and LEMC. 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 fire incident was reported in laboratory from Bunsen burner for in a BSC. The incident was caused by a build-up of Liquid Petroleum Gas (LPG) that had accumulated in the BSC during a three-to-five-minute delay between the turned on the LPG and lit it. As result, while the High Efficiency Particulate Air (HEPA) filters inside BSCs remove particulates and microorganisms, they do not remove fumes from the air inside the cabinet. Furthermore, BSCs are not designed for Bunsen burners to be used inside them (W.H. Al-Dahhan et al. 2016).

In addition, there are reports fire accident in laboratories because they dealing with Flammable material and fire, however, the PTPC, biobank Centre, and LEMC usually do not have flammable materials in the facilities and there is less chance for handling of any Flammable materials. Moreover, in EPHI's 78 years history, there is no any fire incident reported. Annually employees of the institute take training on drill exercise including how to operate fire extinguisher, emergency signs and exit. There are fire extinguisher placed in convenient location of each building including the laboratory and they are regularly inspected. Without provisions for fire safety, there is a risk of fire outbreak in the laboratory with life risk and financial impact.

In EPHI's 78 years history, there is no any fire incident reported. Annually employees of the institute take training on drill exercise including how to operate fire extinguisher, emergency signs and exit. There is fire extinguisher placed in convenient location of each building including the laboratory and

they are regularly inspected. Without provisions for fire safety, there is a risk of fire outbreak in the laboratory with life risk and financial impact.

Duration of the impact would be *long-term* lasting entire life of laboratory operation phase, local in spatial extent affecting onsite facilities, patients, lab workers and neighbouring communities with possibly irreversible impact. The likelihood of the impact occurring, and its intensity are *low* if “facility design” is standard laboratory design and regular fire safety precautions are implemented. However, *sensitivity* on the receptors will be *medium*, thereby giving moderate impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.24 Mitigation measures for impact of fire outbreak

The proposed project would adhere to the application of salient practices from the WBG EHS Guidelines for Community Health and Safety and in section Life and Fire Safety and WHO Laboratory Biosafety Manuals 3rd edition in section Fire Hazards as follow:

- All staff will have training in fire control through regular firefighting drills.
- Fire extinguishers would be available in accessible area near to fire risk area and ensure that all fire-fighting equipment is regularly maintained and serviced.
- Fire emergency telephone numbers would be displayed in communal areas.
- Automatic fire alarm system for the entire laboratory will be installed.
- Fire suppression for the BSL-3 facility would be provided by a standard wet-pipe fire sprinkler system.
- Water flow alarms would be connected to the facilities fire alarm monitoring station so that
- Designated responders would be notified
- Water hose reels will be installed in the laboratory.

- Fire hazard signs such as ‘No Smoking’ signs will be provided. Directions to exit in case of any fire incidence and emergency contact numbers will be provided. The contact/emergency numbers will be displayed within the laboratory.

7.3.25 Chemical hazard in the BSL 3 NRL complex building

Handling of chemicals is a typical routine activity for many lab workers, but the risks and hazards remain the same. Many organic and inorganic chemicals are corrosive to the skin and to the eyes, and can be toxic. Full safety wear should be provided to any members of the team handling chemicals, and provisions to treat any exposure or clean spillages should be present in the laboratory. Chemical hazards represent potential for illness or injury due to single acute exposure or chronic repetitive exposure to toxic, corrosive, sensitizing or oxidative substances. They also represent a risk of uncontrolled reaction, including the risk of fire and explosion, if incompatible chemicals are inadvertently mixed. However, accidents due to chemical never been reported in the institution.

As a research institute as well as a reference laboratory, EPHI use a large amount of chemical for different purposes. Professional has extensive experience in handling of chemicals and takes regular training on chemical handling and storage. Chemical hazards represent potential for illness or injury due to single acute exposure or chronic repetitive exposure to toxic, corrosive, sensitizing or oxidative substances. They also represent a risk of uncontrolled reaction, including the risk of fire and explosion, if incompatible chemicals are inadvertently mixed. However, accidents due to chemical never been reported in the institution.

Occupational chemical exposure may result from laboratory procedures performing and handling of chemicals. The proposed BSL3 NRL project operators would have procedure to prevent chemical hazardous. This control measures would be designed and implemented accordingly and the institute would continue providing training on the appropriate usage, handling and storage of chemicals.. Chemical hazards can most effectively be prevented through a hierarchical approach that includes:

Duration of the impact would be *long-term* lasting through the entire life of the affected person or short-term depending on the hazard exposed to. The intensity of the impact is *low* if appropriate ‘‘facility design’’ is adopted and PPE used by workers. However, *sensitivity* on the receptors will be *high*, thereby giving *moderate* impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.26 Mitigation measures for chemical hazard in the BSL 3 NRL complex building

According to WBG EHS Guideline and Laboratory Biosafety Manual 3rd edition, following the mitigation strategies will be implemented:

- Only small amounts of chemicals necessary for daily use would be stored in the laboratory. Bulk stocks would be kept in specially designated rooms or buildings away from the main laboratory.
- 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
- Where corrosive, oxidizing, or reactive chemicals are used, handled, or stored, qualified first-aid would always be ensured. Appropriately equipped first-aid stations would be easily accessible throughout the place of work, and eye-wash stations and/or emergency showers would be provided close to all workstations where the recommended first-aid response is immediate flushing with water
- Keeping the number of employees exposed, or likely to become exposed, to a minimum
- Communicating chemical hazards to workers through labelling and marking according to national and internationally recognized requirements and standards, including the International Chemical Safety Cards (ICSC), Materials Safety
- Material 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
- The following actions should be taken in the event of a significant chemical spill:
 - Notify the appropriate safety officer.
 - Evacuate personnel from the area.
 - Attend to persons who may have been contaminated.
 - If the spilled material is flammable, extinguish all open flames, turn off gas in the room and adjacent areas, open windows (if possible), and switch off electrical equipment that may spark.
 - Avoid breathing vapor from spilled material and use Powered Air-Purifying Respirator (PAPR).
 - Establish exhaust ventilation if it is safe to do so.
 - Secure the necessary items (see above) to clean up the spill

7.3.27 Electrical and explosive hazards in the BSL 3 NRL complex building

Ethiopian Public Health Institute has sufficient electric power supply from Ethiopian Electric Power and also supported by 24 hours on alert generators in case of power interruptions/failure. Most of the laboratory equipment also has Uninterruptible Power Supply (UPS) to ensure that work doesn't interrupt. The institute has excellent electric hazard record with no electric hazard incident ever been reported. The institution also have permanent technician that oversee and provide maintenance for any electric malfunctioning. The proposed BSL-3 would employ lightning protection designed to meet the requirements.

All Equipment in the laboratory need electric power, without provisions for electrical safety, there is a risk of electric hazard in the BSL 3 laboratory. Exposed or faulty electrical devices, such as circuit breakers, panels, cables, cords and hand tools, can pose a serious risk to workers.

Duration of the impact would be *long-term* lasting entire life of laboratory operation phase, local in spatial extent affecting onsite facilities, patients, lab workers and neighbouring communities with possibly irreversible impact. The likelihood of the impact occurring, and its intensity are *low* if “facility design” is standard laboratory design. However, *sensitivity* on the receptors will be *medium*, thereby giving moderate impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.28 Mitigation strategies for electrical and explosive hazards in the BSL 3 NRL complex building

WBG EHS Guideline and WHO Laboratory Biosafety Manual 3rd edition recommends actions include:

- It is essential that all electrical installations and equipment are inspected and tested regularly, including earthing/grounding systems. Circuit-breakers and earth-fault-interrupters should be installed in appropriate laboratory electrical circuits. Circuit-breakers do not protect people; they are intended to protect wiring from being overloaded with electrical current and hence to prevent fires. Earth-fault interrupters are intended to protect people from electric shock.
- All laboratory electrical equipment would be earthed/grounded, preferably through three-prong plugs.
- All laboratory electrical equipment and wiring would conform to national electrical safety standards and codes
- Disconnect equipment attached to high-voltage or high-amperage power sources from the source or provide a lockout device on the breaker box to prevent circuit activation before maintenance is performed.
- Because electrical devices can generate sparks, do not use them near flammable or volatile gases or liquids.
- Never place flammable liquids in a household refrigerator. The spark generated by the door-activated light switch can ignite fumes trapped in the unit, causing an explosion and fire.
- Specialized refrigerators would be used when storing chemicals that have explosion potential.

7.3.29 Ergonomic hazards in the BSL 3 NRL complex building

Laboratory workers are at risk for repetitive motion injuries during routine laboratory procedures such as pipetting, working at microscopes, operating microtomes, using cell counters and keyboarding at computer and working on BSC workstations. Standing and working in awkward positions in front of laboratory hoods/biological safety cabinets can also present ergonomic problems. By becoming familiar with how to control laboratory ergonomics-related risk factors, EPHI would provide any tool for employees to reduce chances of occupational injuries while improving worker comfort, productivity, and job satisfaction.

Duration of the impact would be *long-term* lasting entire life of laboratory operation phase, local in spatial extent affecting onsite facilities lab workers with possibly impact. The likelihood of the impact occurring, and its intensity are *low* if “facility design” is standard laboratory design. However, *sensitivity* on the receptors will be *medium*, thereby giving moderate impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.30 Mitigation strategies for ergonomic hazards in the BSL 3 NRL complex building

WBG EHS Guideline put Recommendations for prevention and control ergonomic hazards include:

- Training of workers in lifting and materials handling techniques during operation, including the placement of weight limits above which mechanical assists or two-person lifts are necessary
- Planning work site layout to minimize the need for manual transfer of heavy loads
- Selecting tools and designing work stations that reduce force requirements and holding times, and which promote improved postures, including, where applicable, user adjustable work stations
- Implementing administrative controls into work processes, such as job rotations and rest or stretch breaks.

7.3.31 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 ((Kulkarni et al., 2008). 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. The International Agency for Research on Cancer classifies 2,3,7,8 tetra-chlorinated dioxin as a known human carcinogen based on evidence on animal experiments and enough evidence on human studies (Ange et al. 2012). Short-term (called acute) exposures may result in skin lesions and altered liver function. The composition of dioxins in the flue gases exiting the combustion chamber of incinerators ranges from 1 to 500 ng TEQ Nm³. Therefore, it is important to treat the flue gas to reduce its concentration to an acceptable limit (0.1 ng TEQ Nm³) before releasing to the environment (Kulkarni et al., 2008). In that context, ambient air monitoring is an essential issue to estimate pollutant emissions such as dioxins.

During the operation BSL 3 laboratory, 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 SO₂, CO₂, CO, NO_x, 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. Large-scale incinerators tend to pollute less than small-scale incinerators because the combustion temperature is higher and combustion efficiency (gas residence time) is better. To avoid the risk associated with incinerator, it is good that treatment in Pyrolytic or Rotary Kiln Incinerator with good emissions management system.

EPHI is planning to purchase an environment friendly technology incinerator in this project to replace the existing incinerators since these incinerators working for several years. The proposed incinerator that is highly environment-friendly and capable to reduce the pollutant gas, for instance, SO₂, HCl, HF, fine particulate etc. that meet the Europe Union (EU) emission standards, with the technology of smokeless and odourless with burn rate 50 kg/hr.

The new pyrolysis incinerator to be procured by EPHI with a capacity to burn 50 kg per hour with emission reduction device control (Fabric filter coated with catalyst) made from PTFE, with parallel dedusting, lower contamination of filter dusts because of PCDD/PCDF destruction at the catalytic surface that have high efficiency reduction of dioxin upto <0.1 ng TEQ/m³. The new (to be purchased) incinerators would not add to air emissions and would not affect the local air quality besides, they would be active for few hours per day so the emission would be minimal and the impact *intensity* to be *low* when control measures are not instituted and the *sensitivity* on the receptors will be *medium* resulting in a *moderate* impact significance.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.32 Mitigation strategies for impact of air pollution due to waste incineration

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
- New environmentally friendly incinerator would be purchased considering the following features:
 - 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.⁷
 - 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;
 - Minimize the uncontrolled ingress of air into the combustion chamber via waste loading or other routes;
 - Optimize and control combustion conditions by the control of air (oxygen) supply, distribution and temperature, including gas and oxidant mixing; the control of combustion temperature level and distribution; and the control of raw gas residence time;
 - maintenance and other procedures would be implemented to minimize planned and unplanned shutdowns;
 - operating conditions in excess of those that are required for efficient destruction of the waste would be avoided;
 - Auxiliary burner(s) would always be used for start-up and shut-down and for maintaining the required operational combustion temperatures (according to the waste concerned) when unburned waste is in the combustion chamber.

- Flue gas treatment system would be used for control of acid gases, particulate matter, and other air pollutants;
- 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

7.3.33 Impact of noise and vibration

The expected noise levels during operation of the proposed BSL-3 facility would be consistent with those of other existing EPHI research and diagnostic laboratory facilities. These are from the facility’s HVAC system operation, BSC, backup power generator, and another laboratory equipment (such as centrifuge, blender). However, residential areas would not be exposed to ambient noise level greater than 75 dBA beyond the boundaries of the site, nor greater than 55 dBA at the boundary of a residential district.

Though the level of discomfort caused by noise is subjective, the most commonly reported impacts of increased noise levels are interference in oral communication (Stansfeld and Matheson, 2003) and disturbance to some vibration sensitive laboratories equipment housed in EPHI. As the equipment used in the BSL 3 laboratory complex have less noise, impact receptors include staff, patients and their attendants is negligible. The impact *intensity* will be very *low and short term* if an experienced contractor is contracted to carry out the construction activities. However, *sensitivity* on receptors will be very *low*, hence a very *low* impact significance.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.34 Misuse and/or theft of infectious agent, laboratory equipment/supplies in the BSL 3

NRL complex building

Concerns about bioterrorism and recent technological advances in gene synthesis and gene editing have brought the dual use nature of biological research into public focus. The potential for misuse is especially apparent with respect to research on human pathogens. Although less obvious, there is also misuse potential in connection with research involving animal and plant pathogens – or involving no pathogens at all. Indeed, awareness of such misuse potential is needed in virtually all research fields involving use of biological material and development and application of new technologies. Rudimentary biological weapons have been used for centuries. For instance, during the so-called French and Indian War (1754–1767) in North America, British military authorities gave blankets carrying smallpox to Native Americans in a deliberate effort to provoke an outbreak.⁵ During and after World War II, several countries established large-scale biological weapons programs (Whitby et al.2015).

In 1972 the international community agreed on the Biological and Toxin Weapons Convention, banning the development, production, possession, and use of biological weapons by state powers. With the anthrax attacks in the US in 2001, a week after September 11, the focus and concern shifted from state-led bio weapon programs to bioterrorism. To date, there have been very few proven cases of terrorists expressing interest in biological agents, much less trying to acquire them. A comprehensive report on biological weapons in the twentieth century points to approximately 30 cases of biological agents being used or acquired for illicit purposes by non-state actors.⁷ Eight of these cases stem from terrorist groups, and only one bio terror case is known to have resulted in harm to people (see also list below). The remaining cases involved individuals acting on narrower criminal motives such as murder, extortion, or revenge (“biocrimes”). The most common biological agents implicated in acts of bioterrorism and biocrime have been anthrax strains, HIV, and the ricin and botulinum toxins. Criminals and terrorists acquired the biological agents by various means: whether from legitimate suppliers, natural sources, self-manufacturing, or theft. The corresponding report concludes that bioterrorist attacks are low probability events but carry potentially major consequences if they occur (Franziska & Ursula, 2016).

In BSL 3 lab, BSL 2 labs, Biobank and PTPC there would be agents that can be misused and/or stolen. Such a deliberate and/or unexpected misuses and thefts can potentially end up in the release of

microorganisms and biological materials that may affect the environment and community health. In addition, in laboratory there are very expensive types of equipment that can be misused and/or stolen. Such a deliberate and/or unexpected misuses and thefts can potentially end up in the release of microorganisms and biological materials that may affect the environment and community health and affect the function of the BSL 3 NRL complex due to stolen of equipment or supplies.

EPHI employs a computerized data base system called Pathogen Access Control System (PACS) that each lab records the type, amount and location of the microorganisms they housed. Since the establishment of EPHI seven decades ago, there is no report on the misuse and /or theft of equipment, biological and chemical materials. Duration of the impact would be *long-term* lasting entire life of laboratory operation phase, local in spatial extent affecting, lab workers, patients and neighbouring communities. The impact may be irreversible, and its likelihood of occurrence and its intensity are *low* if “facility design has a well-established **Laboratory Security/Biosecurity system**. However, *sensitivity* on the receptors will be *medium*, thereby giving moderate impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.35 Mitigation measures for misuse and/or theft of infectious agent, laboratory equipment/supplies in the BSL 3 NRL complex building

- Strict Biosecurity measures would be implemented to limit access to facilities, research materials and information.
- Continue the use of digital inventory system for both the microorganisms and equipment.
- Develop measures to protect against the insider threat (employees, staff, or contractors), or outsider threat (outsiders who intend to gain access to do harm) and any natural or manmade events that could cause a release.

- Establish system for physical security, personnel security, material control & accountability, and information security
- All staff will have training in laboratory security and biosecurity.
- All BSL 3 lab, BSL2 labs, Biobank and PTPC would be lock always and non-authorized personnel forbidden to enter the facilities without permission.

7.3.36 Gender based violence impacts

The operational activities of the proposed BSL 3 NRL laboratory will have limited interactions with members of the public who will come to deliver samples or collect results. The assessment revealed that occurrence of GBV cases in connection with services provided by the EPHI laboratories to the public is hardly present. This is expected to continue due to the reason that same pattern of services is going to be delivered by the BSL 3 NRL to the public. On the other side, occurrence of GBV cases within the EPHI staff itself is extremely rare mainly due to the nature of the staff which is largely composed of qualified professionals having a sense of conformity to the negative outcomes of GBV. As a result, the potential impacts of the proposed BSL-3 NRL project to aggravate the occurrence of GBV cases is insignificant for it is not going to change the patterns of service delivery to the public and staffing within itself.

Duration of the impact would be *short-term*, local in spatial extent affecting laboratory workers and members of the public (patients). The impact may be reversible, and its likelihood of occurrence and its intensity are *low*. However, *sensitivity* on the receptors will be *medium*, thereby giving minor impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.37 Mitigation measures for gender-based violence impacts

- Conduct continued sensitization and awareness raising to EPHI staff in general and BSL-3 NRL staff on prevention of GBV.
- Strengthen the Gender and women office of EPHI to address GBV cases when it occurs.

7.3.38 Impact due to Improper Waste Management

Health-care activities lead to the production of waste that may lead to adverse health effects. Most of this waste is not more dangerous than regular household waste. However, some types of health-care waste represent a higher risk to health. These include infectious waste (15% to 25% of total health-care waste) among which are sharps waste (1%), body part waste (1%), chemical or pharmaceutical waste (3%), and radioactive and cytotoxic waste or broken thermometers (less than 1%). Although sharps waste produced in small quantities, is highly infectious. Poorly managed sharp wastes could expose the healthcare workers, waste handlers and the community to infections. Contaminated needles and syringes represent a particular threat and may be scavenged from waste areas and dump sites and be reused. WHO has estimated that, in 2000, injections with contaminated syringes caused: 21 million hepatitis B virus (HBV) infections (32% of all new infections); 2 million hepatitis C virus (HCV) infections (40% of all new infections); 260 000 HIV infections (5% of all new infections).

Epidemiological studies indicate that a person who experiences one needle-stick injury from a needle used on an infected source patient has risks of 30%, 1.8%, and 0.3% respectively to become infected with HBV, HCV and HIV. In 2002, the results of a WHO assessment conducted in 22 developing countries showed that the proportion of health-care facilities that do not use proper waste disposal methods ranges from 18% to 64%. Health-care waste management options may themselves lead to risks to health and no perfect readily achievable solution to manage health-care waste exists. Health-care waste, whether generated at smaller rural clinics or larger facilities, can be managed where adequate well-operated infrastructures exist. However, the volumes of waste generated within large facilities and targeted public efforts (e.g., immunization campaigns) are more challenging, particularly in developing countries where resources may be limited. In these difficult situations for which waste disposal options are limited, small-scale incinerators have been used and are still used as an interim solution in less developed and transitional countries.

The WHO confirms the risks associated to infectious waste and sharps that health professional are exposed to during healthcare delivery and also exposed to such risks during waste collection, storage, transport, treatment and disposal. Furthermore, risks because of chemical and pharmaceutical wastes are associated with the characteristics of the chemical substance such as its toxicity and flammability. These wastes are generated when they are unwanted or have been expired and may cause poisoning if absorbed through the skin, inhalation or ingestion. Similarly, the final disposal of hazardous waste that is incineration, involves health risks to which the operators are exposed to medical waste incinerators emit of toxic gases such as Dioxin which are detrimental to health (Bokhoree et al. 2014). However, small-scale incinerators often operate at temperatures below 800 degrees Celsius. This may lead to the production of dioxins, furans or other toxic pollutants as emissions and/or in bottom/fly ash. Transport to centralised disposal facilities may also produce hazards to health-care handlers, if not safely managed. Therefore, risks associated with waste management are expected during waste collection, storage, transport, treatment and disposal. And risks and impacts with mitigation measures are summarized below.

7.3.39 Risk associated with collection/handling and storage of waste at BSL 3 NRL complex building

During the operational phase of the BSL 3 laboratory it is anticipated that solid and liquid wastes are generated daily. Most of the BSL-3 wastes generated would be considered as highly infectious but there would be non-hazardous waste generated from BSL 2 laboratories, PTPC, Biobank Centre and LEMC. Since laboratory activities involve certain medical examinations and there will be a need for usage of different sorts of chemicals or reagents, it can be predicted that different types of hazardous wastes shall be generated. Therefore, improper handling, treatment and disposal waste can cause serious health problem for workers, community (death, illness) and environment (i.e. impaired air quality, contamination of water courses). The expected waste quantities and treatment and disposal practices described above for BS 3 lab.

The expected healthcare infectious/hazardous waste would be 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 diagnosis.

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. Examples of the types of healthcare waste expected to be generated from the proposed BSL 3 laboratory during the operational stage are summarized in section 2.6.2. Likelihood of the impact occurring is low since EPHI is a pioneer in laboratory service, has experience and established system in healthcare waste management the wastes that generated from existing mobile BSL 3 laboratory, and if the WHO laboratory biosafety manual and WBG EHS healthcare waste management would be implemented during the operation of BSL 3 laboratory. It is a long-term impact, local and cumulative in nature and with increased laboratory activities the *intensity* of the impact will be *low*. *Sensitivity* of receptors due to improper medical waste management is *medium*, thereby giving major impact significance.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.40 Mitigation strategies for risk associated with collection/handling and storage of waste at BSL 3 NRL complex building

The proposed BSL-3 NRL would adhere to the application of The Ethiopia Healthcare Waste Management National Guideline 2008, WHO Laboratory Biosafety Manual 3rd edition and WBG EHS Guidelines which represent best practices and experiences in innocent and hazardous waste management.

- Develop and implement a waste management plan for EPHI in general and for the proposed NRL project in particular in accordance with the infection control and waste management plan to guide the daily waste management operations.
- Initial packaging and storage would take place where HCW is generated.
- Storage of waste will then be moved to a temporary on-site storage location

- Non-risk HCW would always be stored in a separate location from the infectious/ hazardous HCW in order to avoid cross-contamination.
- Strengthen the internal waste management system (collection, storage and disposal) of the EPHI and equip it with additional facilities to allow for segregated collection at source.
- All sharps used in the BSL-3 would be autoclaved prior to incineration.
- 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.
- Solid waste generated in the BSL-3 laboratory would leave the laboratories only after decontamination using the laboratory's autoclave.
- Non-hazardous wastes that are generated by the BSL-3 would be incinerated.
- Liquid Waste discharged from laboratory would be treated chemically prior to being released to the waste tank.
- Additional septic tank would be constructed at EPHI to improve the capacity of the tank.
- Provide appropriate waste bins (colour coded) for the different types of waste generated in the BSL 3 NRL to allow segregation and collection at the point of generation. The autoclaving process involves placing waste to be autoclaved in a special container. Indicator would be used to assess the proper functioning of the autoclave. The autoclave performance also automatically tracked electronically to insure its effectiveness. The collection of autoclaved waste should be made at least once in 24 hours, and disposed by incinerator
- Laboratory staff and all other staff involved in waste handling would be trained on the waste handling treatment, and disposal techniques.
- Fumigation of the laboratory by disinfectant gases would be conducted according to WHO laboratory manual.

- Regular visual inspection of all waste storage collection and storage areas for evidence of accidental releases and to verify that wastes are properly labelled and stored.
- Regular audits of waste segregation and collection practices.
- Tracking of waste generation trends by type and amount of waste generated, preferably by facility departments.
- Keeping manifests or other records that document the amount of waste generated and its destination.

7.3.41 Risks associated with waste transportation within EPHI campus

Medical waste may contain potential pathological organisms which if improperly managed may be a risk to healthcare staffs and public during transportation. In the 1980s and 1990s, issues concerning exposure to HIV along with Hepatitis B Virus (HBV) led to rising concerns of potential risks evolving due to medical waste. Therefore, waste generated from healthcare facilities has become a focal point due to its several consequences as a threat to the health of patients, health care staff and outside the medical establishment. Moreover, health care workers are not very much aware of the risks associated with medical waste. Studies have shown personnel dealing with medical waste are by the biological, physical and chemical hazards such as needle sticks, cuts, falls, strains, sprains, burns, eye and back injuries during collection, handling and transportation. Several injuries such as hand cut due to handling broken glass occurred due to exposure to medical wastes inside and outside hospital premises (Bokhoree et al. 2014). During the transportation of waste, there might be releasing of waste to environment

All individuals exposed to healthcare waste are potentially at risk of being injured or infected. Waste management and treatment options should first protect the healthcare workers and the population and minimize indirect impacts from environmental exposures to HCW. During transporting/handling of wastes, the laboratory and ancillary staff as well as the sanitary labourers can be injured if the waste has not been packed safely. In that respect, sharps are considered as one of the most dangerous categories of waste. Many injuries occur because syringe needles or other sharps have not been collected in safety boxes or because these have been overfilled. The public can be infected by medical waste either directly or indirectly through several routes of contamination during transportation of the waste.

During transportation, waste would be released from the container or bags due to poor handling or packaging, these wastes may contain potentially harmful microorganisms that can infect, health workers, patients and the general public as well as the environment. Other potential hazards may

include drug-resistant microorganisms which spread from health facilities into the environment. So, the adverse health outcomes associated with health care waste transportation would be infected by highly infectious agents, sharps-inflicted injuries; chemical burns arising in the context of disinfection, sterilization or waste treatment activities.

These constitute a grave risk, if they are not properly handled, and transported to EPHI treatment facility (incinerator). The types of waste expected to be generated from the proposed BSL 3 laboratory complex building during the operational stage likelihood of the impact occurring is low since EPHI is a pioneer in laboratory service, has experience and established system in healthcare waste management the wastes that generated from existing BSL 2 laboratories and mobile BSL 3 laboratory, and if the WHO laboratory biosafety manual and WBG EHS healthcare waste management would be implemented during the operation of BSL 3 laboratory complex building. It is a long-term impact, local and cumulative in nature and with increased laboratory activities the *intensity* of the impact will be *low*. *Sensitivity* of receptors due to improper medical waste management is *medium*, thereby giving major impact significance.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low 1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.42 Mitigation Strategies for risks associated with waste transportation within EPHI campus

On-site transportation would take place whenever possible during less busy times (i.e. in the evenings or very early morning).

- Set routes would be used to prevent exposure to staff and patients and to minimize the passage of loaded carts through patient care and other clean areas.

- All waste bags would in-place and intact at the end of transportation;
- Carts, trolley, or containers used for the transportation of infectious waste would not be used for the transportation of any other material; and would be used for transporting safety boxes and bins
- A trolley, bin, or wheelbarrow will be used for transporting safety boxes and bins.
- Waste that has the potential to leak will 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
- The collected waste will not be left even temporarily anywhere other than at the designated storage room.
- Containers would be covered with lids during storage and transport.
- The internal transportation of waste would use separate floors,
- Regular transport routes and collection times would be fixed and reliable.
- Transport staff would wear adequate personal protective equipment (PPE) including gloves, closed shoes, overalls and masks.
- Education and training would be provided to all waste transport workers and include how to safely handle waste containers that leak or are broken.
- A bulky and heavy waste would be transported by using wheeled trolleys or carts that are not used for any other purpose.
- Waste, especially hazardous waste, would never be transported by hand due to the risk of accident or injury from infectious material
- The vehicles would be thoroughly cleaned and disinfected daily as per a written protocol.
- Separate routes for transporting hazardous and non-hazardous waste would be used. In general, a waste route would follow the principle from “clean to dirty”.
- Collection would start from the most hygienically sensitive laboratory area

7.3.43 Risk associated with off-site transport of waste

The off-site transport of waste from generator facilities to treatment facilities imposes a population health risk associated with potential accidents involving the release of infectious agent and toxic chemicals to the atmosphere. These transports also impose a potential collision health risk to other

vehicle drivers and passengers, pedestrians, and the transport truck crew members. However, EPHI would transport bottom and fly ash and treated liquid waste, there is no any potential accidents involving the release of infectious agent.

During transportation of bottom and fly ash to final disposal site and liquid waste, there will be a linkage or spillage of the waste from the vehicle due to poor packaging of the waste and car accident. Resulting high risk for community and environmental due to dioxins and heavy metals released from the waste. The characteristic of these wastes are that they are enriched with heavy metals, and the large amount of Zn and Cr in MW may come from syringes, waste plastics, rubber, and medical adhesive plaster. Heavy metals in the waste usually present as metal oxides, metal elements, volatile metallic chlorides, and sulphates. Most heavy metals migrate or concentrate in the fly ash and bottom ash; depending on the formed compounds of heavy metals and their physicochemical properties during incineration. These constitute a grave risk, if they are not properly transported from EPHI treatment facility (incinerator) to final disposal site.

As EPHI has experience and established system in healthcare waste management the wastes that generated from existing BSL 2 laboratories and mobile BSL 3 laboratory, safe Off-site transportation of waste would be conducted to prevent or minimize spills, releases, and exposures to employees and the public. In addition, if the WHO safe waste management and WBG EHS healthcare waste management guidelines would be implemented during transportation of the waste. It is a long-term impact, local and cumulative in nature and with increased laboratory activities the *intensity* of the impact will be *low*. *Sensitivity* of receptors due to improper waste transport is *medium*, thereby giving major impact significance.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.44 Mitigation measures for risk associated with off-site transport of waste

Additional recommendations specifically applicable to hazardous waste collection and transport operations include:

- EPHI would follow applicable national regulations and internationally accepted standards for packaging, labelling, and transport of hazardous materials and wastes;
- All waste containers designated for off-site shipment would be secured and labelled with the contents and associated hazards, be properly loaded on the transport vehicles before leaving the site, and be accompanied by a shipping paper (i.e., manifest) that describes the load and its associated hazards
- EPHI would use tanks and containers specially designed and manufactured to incorporate features appropriate for the wastes they are intended to carry; If drums or other containers are used to transport waste, containers should be in good condition and compatible with the waste and are adequately secured in the transport vehicle;
- EPHI would adequately label all transport tanks and containers to identify the contents, hazards, and actions required in various emergency situations.
- The waste would be placed in rigid, leak-proof containers before being loaded.
- Containers would be covered with lids during transportation.
- When transporting plastic bags of infectious waste, care should be taken to prevent tearing the bags.
- Vehicles used for transporting infectious waste shall be disinfected prior to use for any other purpose.

- The vehicles shall carry adequate supplies of plastic bags, protective clothing, cleaning tools, and disinfectants to clean and disinfect in case of any spills.
- Records must be kept documenting all transport of medical waste

7.3.45 Risk associated with final waste disposal

The wastes generated from different processes are of complex characteristics and composition and hence, their safe management and disposal is also complex. The disposal and storage of these wastes without treatment leads to contamination of surface and groundwater through long term leachate accumulation from the disposal sites and ultimately disturbs the ecological and environmental balance. The characteristic of these waste are that they are enriched with heavy metals, and the large amount of Zn and Cr in MW may come from syringes, waste plastics, rubber, and medical adhesive plaster. Heavy metals in the waste usually present as metal oxides, metal elements, volatile metallic chlorides, and sulphates. Most heavy metals migrate or concentrate in the fly ash and bottom ash; depending on the formed compounds of heavy metals and their physicochemical properties during incineration.

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 (Ange et al. 2012). Short-term (called acute) exposures may result in skin lesions and altered liver function. In addition, the heavy metals released from the waste are toxic and mutagenic properties related to its oxidizing activity.

During the operation BSL 3 laboratory, wastes 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 SO₂, CO₂, CO, NO_x, particulates and other toxic substance. 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 bottom and fly ash and sludge, it is good that treatment in Pyrolytic incinerator with good emissions management system to minimize the production of dioxins and heavy metals and dispose at dedicated area for disposal.

As EPHI has experience and established system in healthcare waste management (disposal) the wastes that generated from existing BSL 2 laboratories and mobile BSL 3 laboratory, safe off-site disposal of bottom and fly ash and sludge waste would be conducted to prevent releases, and exposures to public and environment of dioxins and heavy metals from the waste. If the WHO safe waste management and WBG EHS healthcare waste management guidelines would be implemented during waste disposal. It is a long-term impact, local and cumulative in nature and with increased laboratory activities the *intensity* of the impact will be *low*. *Sensitivity* of receptors due to improper waste transport is *medium*, thereby giving major impact significance.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.46 Mitigation Strategies for risk associated with final waste disposal

- Personnel working on waste disposable would wear adequate personal protective equipment (PPE) including gloves, closed shoes, overalls and masks.
- Training would be provided to personnel working on waste disposable
- Bottom ash would be managed separately from fly ash and other flue gas treatment residues to avoid contamination of the bottom ash for its potential recovery;
- Remaining ferrous and non-ferrous metals would be separated from bottom ash as far as practicably and economically viable, for their recovery;
- bottom ash would be treated on-site by screening and crushing to the extent that is required to meet the specifications set for its use or at the receiving treatment or disposal site (e.g., to achieve a leaching level for metals and salts that follows the local environmental conditions at the place of use);
- Bottom ash and residuals would be managed based on their classification as hazardous or non-hazardous materials.

- Hazardous ash would be managed and disposed of as hazardous waste.
- These wastes are predominantly hazardous wastes and would be disposed of in safe landfills, and the landfilling would be in proper double-walled containers.
- Waste disposal system would be monitored periodically

To avoid the impacts raised from the fly ash and flue gases the EPHI will propose to utilize the primary strategies (operation by trained, qualified personnel, use of personal protection equipment, periodic maintenances, Auditing and reporting systems and routine inspection of furnace and air pollution control systems) and secondary strategies like fabric filter coated with catalyst made from PTFE, with parallel “de-dusting” to remove most of the fly ash, lower contamination of filter dusts because of PCDD/ PCDF destruction at the catalytic surface with high efficiency (< 0.1 ng TEQ/m³ with Cement Solidification Technology (CST) and then encapsulated in double containers made from polyethylene material to transport in safe manner to disposal site utilized by Kotebe waste treatment plants for landfilling. Alternatively, the homogeneous mixture can be transported in liquid state to a kaliti wastewater treatment plant and then the treated sludge will be disposed in secured manner at landfilling disposal site utilized by Addis Ababa water and sewerage Authority.

As plan B, Sendafa Sanitary landfill will be considered for final disposal of handling incineration residues if this would be socially and environmentally feasible. The updating of the ESIA, ESMP and ICWMP during implementation will also consider the assessment of the capacity of Kotebe waste treatment plant and Sendafa sanitary landfill for handling incineration residues.

7.3.47 Impacts of Improper waste water treatment at EPHI BSL 3 NRL Complex

Several risk factors can reduce the efficiency of the septic tank. The risk can be imparted during designing or operation phase. During designing phase if risks such as Inadequate tank volume, geometry and compartmentalization, inconsideration of tank access space and plan that involves the use of substandard construction materials are not managed properly it can reduce the efficiency of the septic tank treatment system. In addition, a faulty designing can result also in cracking of the tank, leakage (ground infiltration), tank flotation and inadequate retention time of effluent. Moreover, scums, septage and sludge can clog the septic tank drainage system. on the other hand, similar problems can reduce the efficiency of sand/media filters. For instance, low retention time, minimum

aeration, undesirable pore size distribution, dose volume and frequency key risk factors that hamper efficiency of sand media filter.

In relation to suspended growth aerobic systems - clarifier operation common operational problems of aeration tank are but not limited to excessive local turbulence in aeration tank, white thick, billowy foam on aeration tank, clumps of rising sludge in clarifier, fine dispersed flocs, and turbid effluent.

Moreover, natural organic matter or the fraction of TOC in the water in the form of particulate matter (such as suspended solids, turbidity or colour) can reduce the performance of UV-irradiation.

Compounds that present in the water can also foul the external surfaces of the lamp sleeves and other wetted components of UV reactors which

Faults from designing and operation of the treatment can last for long-term and have high impact on the quality of ground water table, soil and receiving surface water. However, if proper risk mitigation strategies are in place and with the current good septic tank management techniques built in EPHI, the occurrence of impacts on the receptors will be low, thereby giving low impact significance.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.48 Mitigation strategies for impact of Septic tank and sand/media filters operation

- Considering proper tank volume, geometry and compartmentalization to impart adequate hydraulic residence time for sedimentation.
- Elongated tanks with length-to-width ratios of 3:1 or more is will be used to reduce short-circuiting of the effluent
- Two compartments will be used to achieve, better suspended solids removal rates

- Manways 18 to 24 inches in diameter or square will be designed to access the tank for regular monitoring and maintenance.
- Use of Premanufactured, pre-cast concrete, fiberglass, polyethylene and coated steel tanks
- Tank joints will be designed for water tightness
- tank will be located where it can be accessed easily for septage removal and sited away from drainage swales or depressions where water can collect. Maintaining minimum horizontal setback distances from buildings, property boundaries, wells, water lines, and the like.
- Tank will rest on uniform bearing surface
- The backfill material will be free flowing and free of stones larger than 3 inches in diameter and debris
- Joints will be sealed properly, including tank joints
- Use of appropriate anti-flotation devices
- Tanks would be pumped when sludge and scum accumulations exceed 30 percent of the tank volume or are encroaching on the inlet and outlet baffle entrances.
- Periodic pumping of septic tanks will be used to ensure proper system performance and reduce the risk of hydraulic failure.
- Septic tanks will be pumped every 3 to 5 years depending on the size of the tank.
- Pumping and cleaning of Sludge and septage from the septic tank will be outsourced to Addis Ababa water supply and sewerage authority, Kotebe treatment plant.
- To achieve acceptable treatment in the sand/media unit, the wastewater retention time in the filter will be sufficiently long and reaeration of the media will occur to meet the oxygen demand of the applied wastewater. The pore size distribution and continuity of the filter medium, the dose volume, and the dosing frequency will be key design and operating considerations for achieving these conditions.
- Remove and clean or replace the throttle blower as required
- Check aeration system, aeration tank dissolved oxygen level.
- Increase sludge return rate to decrease sludge retention time in clarifier
- Effective cleaning of UV-lamp sleeves periodically.
- In order to improve transmittance of UV, the process control will be implemented to obtain a turbidity level of <0.2 NTU in the final water. Where the turbidity levels are above 0.2 NTU

and/or TOC levels are in excess of 2-3 mg/litre, sludge or waste water return lines will be constructed for better performance.

7.3.49 Analysis of Abnormal Events and Accidents for Facility Operation

7.3.49.1 Laboratory-acquired infection

Laboratory-acquired infections are those infections acquired by workers due to the routine performance of their duties. When the exposure to an infectious agent occurs during an event, it is often considered an accident (such as a needle-stick). When the exposure occurs incidentally during contact with a contaminated surface, it is considered a routine health risk. The following discussion deals only with the accidental laboratory-acquired infection.

Surveillance of laboratory acquired infection (LAI) is, therefore, an efficient marker to evaluate the effectiveness of biosafety and to optimize the risk assessment in BSL 3 laboratories. Before the era of containment laboratories, the 10 microorganisms responsible for >50% of LAI were brucellosis, Q fever, viral hepatitis, typhoid fever, tularemia, tuberculosis, dermatomycoses, Venezuelan equine encephalitis, psittacosis, and coccidioidomycosis. It was reported that 85% of LAI were caused by *Mycobacterium tuberculosis*, *Coxiella burnetii*, Hantaviruses, arboviruses, hepatitis B and C viruses, *Brucella* spp., *Salmonella* spp., *Shigella* spp., and *Cryptosporidium* spp (Byers and Harding 2006).

In the USA, from 2004 to 2010, only 11 LAIs were reported to CDC for microorganisms listed as Biological Select Agents and Toxins, 6 cases due to *Brucella* spp., four cases due to *Francisella tularensis*, and one case due to *Coccidioides immitis/ posadasii*. Although there is no harmonized system for the reporting of laboratory incidents and accidents at the EU level, few LAIs have been described in European laboratories during the last decade highlighting a drastic reduction of these accidents in BSL3 laboratories. Doubtless, current practices have also minimized worker's pathogen exposition and improvements in containment equipment, engineering controls, and safety training contributed greatly to this reduction (Pastorino et al. 2017). There has been an extremely low incidence of laboratory-acquired infections associated with operations in CDC-registered laboratories. The incidence of infection appears to be much lower today in large part due to decreased laboratory activity levels since 1968, and in part due to greatly improved preventive measures.

²Water Treatment Manual: Disinfection. office of environmental enforcement, environmental protection agency, Ireland.
https://www.epa.ie/pubs/advice/drinkingwater/Disinfection2_web.pdf

Control of infection in laboratories has achieved a high level of sophistication, to the point that virtually no reports of infection occur in microbiological laboratories. The CDC says that common acceptance of standard laboratory practices indicates that laboratory-acquired infections should be virtually non-existent today (CDC 1999). However, they do still rarely occur, and the primary route of exposure is through autoinoculation by the unintentional injection or needle stick (Sewell 1995). Needles would be used in the proposed BSL-3 facility. Broken glass with sharp edges could result from accidents with (infrequently used) glassware. Broken glass, needle sticks or even scalpels present a low likelihood of exposure but are obvious when they happen and can be promptly treated with antibiotics, antiviral drugs, or other appropriate medical strategies. The potential for accidental laboratory-acquired infection by these means would be reduced to the improbable level of occurrence.

7.3.49.2 The Laboratory Release Accident Scenario

The potentially hazardous material to be handled in the proposed BSL 3 facility would consist of infectious microorganisms in containers holding liquid suspensions or on semi-solid media. Accident scenarios usually catastrophic events such as earthquake, fire, explosions and airplane crashes, normally considered as initiating events are having the potential to increase risk on microbiological material releases. An earthquake, explosion, or similar event that would result in a breach or rupture of the facility's walls would be bounded by the hypothetical centrifuge-accident analysis of a *Coxiella burnetti* release from the proposed BSL-3 facility structure described later in this section. The probability of catastrophic events (due to earthquake) is already very low. The low probability of an earthquake capable of rupturing the facility containment, coupled with an additionally low probability of such an event occurring during a daytime activity where microorganism containment would be vulnerable, also makes it an unlikely event. The proposed laboratory hypothetical centrifuge accident-release scenario, which itself is very unlikely due to the simultaneous occurrence of several events/conditions that would be combined to produce a release, bounds the catastrophic release scenario.

The BSL-3 facility would have only a few operations or activities that would hypothetically place small volume quantities of material containing infectious organisms at risk at any point in time. These operations or activities would occur at infrequent times and a release to the environment from a catastrophic event would require several simultaneous conditions to coexist: a worker is transferring a quantity of infectious material when the catastrophic event occurs; the containers aren't properly

sealed; the entire set of containers is dropped; the containers break open; and the catastrophic event simultaneously causes a structural breach in the BSL-3 containment walls. Engineering and procedural controls minimize opportunities for this hypothetical scenario. For example, culture samples would be kept in locked freezers or within incubation chambers most of the time and would not become aerosolized in such an event. Therefore, catastrophic events capable of resulting in a substantial release of microorganisms from the confinement of the facility (specifically at greater than infectious dose quantities) would be unlikely to occur.

A literature in BSL-3 laboratory regulators and operators (CDC, NIH, and the U.S. Army) revealed no incidents of infectious materials released from catastrophic accidents at microbiological laboratories. According to the U.S. Army the likelihood of such catastrophic occurrences is too small to be considered as reasonably foreseeable. No such event has occurred in the more than 50 years in which the military has been conducting biological defense research activities. Based on this historical information, this hypothetical scenario was not analyzed further in this ESIA. Historical information suggests that other types of accidents would be reasonably foreseeable; these could involve infectious material. Accidents involving the production of aerosols during the use of normal laboratory equipment such as centrifuges, blenders, homogenizers, shakers, sonicators, and mixers are reported (CDC 1999). According to *Laboratory-Associated Infections and Biosafety*, this is the second most common route of exposure, the first being laboratory-acquired infection due to needle-sticks (Sewell 1995). Even though these accidents are more frequently reported, they rarely result in workers actually contracting diseases due to the use of vaccines and drug therapies.

The rickettsial microorganism, *C. burnetii*, is considered representative of all types of BSL-2, and BSL-3 laboratory microorganisms (bacteria, rickettsia, viruses, fungi, parasites, and prions) because it is highly durable, infectious, and transmissible, and has excellent environmental survivability. Other types of microorganisms were considered for accident scenarios but rejected for specific analysis because they represent a relatively lower human health hazard (fungi and parasites) or have a generally lower environmental survivability (specifically, the prions and viruses). All animal prions and human parasites are Risk Group 1 or Risk Group 2 microorganisms. Only one fungus identified by the CDC requires BSL-3 and all the rest only require BSL-2 or below. Many viruses require BSL-3 procedures and equipment but cannot survive long in the environment without a host such as a human or other animal. Bacteria and their subcategory, rickettsia, represent a high risk to human health and many require BSL-3 or BSL-4 procedures and equipment. (CDC 1999). Of the bacteria,

C. burnetii is a durable rickettsia that can be handled in the laboratory with little or no loss in viability. It can survive being aerosolized and remain viable, although once separated from a nutrient food source, it dies off at a slow rate. This microorganism can be as infectious as any other microorganism. The CDC reports that exposure to only 10 microorganisms can cause an individual with normal immunocompetency to develop symptoms of disease.

The potentially hazardous material to be handled in the proposed BSL 3 facility would consist of infectious microorganisms in containers holding liquid suspensions or on semi-solid media. Since its inception 78 years ago, EPHI laboratory facilities (TB and Other Bacterial & Mycotic Diseases, HIV and other viral, Malaria and other parasitic and, Zoonotic diseases) achieved a high level control of infection in laboratories, to the point that virtually no reports of infection occurred. The low probability of an earthquake at EPHI capable of rupturing the facility containment, coupled with an additionally low probability of such an event occurring during a daytime activity where microorganism containment would be vulnerable, also makes it an unlikely event. The proposed BSL 3 laboratory hypothetical centrifuge accident-release scenario, which itself is very unlikely due to the simultaneous occurrence of several events/conditions that must be combined to produce a release, bounds the catastrophic release scenario. Annex 4 provides the list of Ethiopian selected hazardous agents' information.

Thus, catastrophic events capable of resulting in a substantial release of microorganisms from the containment of the facility (specifically at greater than infectious dose quantities) would be unlikely to occur. However, the duration of the impact would be *long-term* lasting entire life of laboratory operation phase, local in spatial extent affecting onsite facilities lab workers with possibly impact. The likelihood of the impact occurring, and its intensity are *low* if compliance with laboratory standards and good laboratory practices. However, *sensitivity* on the receptors will be *medium*, thereby giving moderate impact *significance*.

Impact significance:

		Sensitivity of receptor			
		Very low 1	Low 2	Medium 3	High 4
Intensity of impact	Very low 1	1 Negligible	2 Minor	3 Minor	4 Minor
	Low 2	2 Minor	4 Minor	6 Moderate	8 Moderate
	Medium 3	3 Minor	6 Moderate	9 Moderate	12 Major
	High 4	4 Minor	8 Moderate	12 Major	16 Major

7.3.49.3 Mitigation strategies for the laboratory release accident scenario

Therefore, this hypothetical accident can be used as a bounding accident analysis for the proposed action in EPHI BSL-3 facility. However, it is exceedingly conservative. From a slightly more realistic perspective, there are some aspects of this accident scenario that would significantly lessen the possible outcome to the point that it would not produce even at the end of the stack in the case of the proposed facility at EPHI. Some of these are:

- Cultures in a centrifuge in their stationary phase (with 10^8 cells per ml) would quickly pack to the bottom of the centrifuge tube and the upper liquid phase that would become aerosolized would have very few cells (depending upon when the accident occurred in the cycle) – therefore the concentration of cells in the aerosol would likely be many orders of magnitude below that used for the analysis (extremely conservative).
- At EPHI and most small BSL-3 laboratories normally only two workers would be allowed in BSL-3 laboratory at a time for safety reasons.
- In an emergency response mode, the responder would enter only after ascertaining the risk and donning appropriate personal protective equipment.
- Facility would have an emergency preparedness and response plan
- The workers would have the appropriate prophylaxis available or immunization prior to working in the laboratory and would not become symptomatic.
- If all the room air were doubly HEPA-filtered with each at a minimum of 95 percent efficiency, the overall filtration would be 99.75 percent efficiency (passing through the first filter with 95

percent efficiency would leave 5% to pass through and the second filter would remove 95 percent of the 5 percent – resulting in 99.75 percent overall removal efficiency).

- HEPA filtration is rated at 99.97 percent efficient at the most penetrating design point of 0.3 microns using the standard for calibration and measurement which is a uniform size, shape, and non-charged. Removal efficiency is not based upon size alone because there are several physical processes which actually cause the particulate removal.
- Penetration of larger- or smaller-sized particulates than 0.1 to 0.3 microns (the most penetrating size range) is negligible (less than 0.03 percent). Actual microbes, especially wet, have biofilms on their surfaces, are not uniform in size or shape, agglomerate together, and would not likely penetrate even at 95 percent efficiency because of their physical characteristics.
- The hypothetical accident results of even these extremely small effects rely on compounding of several independent actions whose combined probability of sequential occurrence would be extremely low (o-rings are not inserted, caps not screwed on properly, all six tubes leak, the worker opens the lid not realizing the tubes leaked, the worker gets two other workers to come over and look, and four more enter not knowing what has happened).
- The aerosol efficiency of 0.1% assumed for the scenario is at least one order of magnitude higher than would be likely in a real situation.
- Increases in wind speed over the modelled rate of 4.5 mph would increase aerosol dilution while humidity (not considered by the model) enhances the settling of particulates and would also decrease airborne concentrations.
- The normal high rate of air-changes for a laboratory like this would not generate a single “concentrated slug” of aerosolized material to exit the building as proposed in the model.
- Risk Group 3 agents (those handled in BSL-3 laboratories) are associated with serious or lethal human diseases for which preventative or therapeutic intervention may be available (high individual risk but low community risk).
- Detailed mitigation measures for laboratory release accident scenario are outlined in the **emergency preparedness and response section 7.3.52 below**. In addition, the proposed BSL-3 laboratory would adhere to the application of the WHO laboratory biosafety manual, and CDC Guideline recommendations for prevention and control release of infectious agents during emergency case.

In conclusion, the community would have a very low likelihood of being exposed to even a small fraction of the agents. At EPHI, the nearest member of the community is about one 500 m away. Adverse health effects to uninvolved workers in adjacent buildings or the public would be extremely unlikely to develop from this scenario. Similarly, adverse effects to the environment from the accidental release of non-indigenous organisms would be extremely unlikely as well.

7.3.49.4 Transportation Accident

Infectious substances or agents in transit on the highways and airports are regulated by the FMHACA regulation. A report showed that the general population risk report by DOT from 1994 to 1998 from all hazardous materials transportation is 1 in 8,129,000, or as otherwise stated, 0.11 fatalities per million shipments (DOT 2001). By comparison, the general population risk per year for motor vehicle accidents is 1 in 6,300 or 1.7 deaths per 100 million vehicle miles (161 million km). The number of hazardous materials shipments is about 800,000 per day with at least 10,000 involving waste hazardous materials identified generally as medical wastes and various other hazardous materials. For the hazardous materials category that includes infectious substances, about 80 percent of these shipments are carried by truck with the remainder carried by rail (DOT 1998). There are an estimated 4,300 non-hospital waste generating facilities (laboratories) that are potential generators of medical waste and other kinds of infectious substances including diagnostics specimens (DOT 2001).

Accidents due to transportation of microorganisms are not expected to increase due to the proposed action. The addition of millilitre-quantity samples shipped to and from the BSL-3 facility through federal or by commercial or private courier would not be expected to change the overall incidence of risk of transportation accidents. Samples could consist of cells in media contained within triple package certified packages. The consequences of such accidents would be anticipated to be minor, based on the historical data. Although there is no any study in Ethiopia, EPHI has never had a biological-material transportation incident.

7.3.49.5 Accidents of incinerators and incinerator failure

Waste management activities are not only a potential source of chronic risks (atmospheric pollution, olfactory or noise nuisances, etc.), they may also be responsible for the risk of accidents. Waste handling/treatment activities are more prone to accidents in proportion to the increased "upstream" risks of collection, sorting, transfer, etc. Fire appears to be the most frequent hazard, which seems

logical, given the combustible and sometimes flammable nature of waste. The consequences of accidents occurring at waste management facilities are, on the whole, less serious than those stemming from events arising in most other industrial sectors.

Despite the diversity and heterogeneity of waste processed at collection and treatment facilities, recurrent accident scenarios are nonetheless identifiable: loss of process control (self-ignition, reaction due to incompatibility), ignition due to an exogenous factor (hot spots, malicious acts), loss of equipment confinement causing environmental pollution, etc. A waste incineration is linked with the problem of solid, liquid, and gaseous materials containing high concentrations of toxic substances. This is further connected with the risk of their releases into the environment, which may take place both by means of gasses formed during the incineration, and during handling of solid residues of incineration and waste waters.

There are also obvious risks associated with the oil/gas to be used for the incinerator is the risk of a fire or explosion. Fire and explosion can result in catastrophic consequences, causing serious injuries or death of workers and others, as well as significant damage to property. A hazardous area is an area in which a flammable atmosphere is or may be expected to be present, and require special precautions for the construction, installation and use of equipment. Examples of hazardous areas are:

- flammable liquid and gas storage tanks and associated equipment
- storage areas for flammable liquids in packages (e.g. warehouses, store rooms,)

Key control measures for managing these risks include:

- identifying and managing hazardous areas
- use of ventilation systems to control vapors during both normal and abnormal conditions (e.g. leak or spill)
- eliminating ignition sources from hazardous areas
- installing systems to detect leaks of flammable gases or vapours and enable response actions to be taken
- using intrinsically safe or flameproof equipment

Possible accidents represent a big danger connected with operation of incinerators. In view of nature and amount of waste to be incinerated, and handled in the incinerator premises, accidents may have a huge impact on the surroundings of these facilities, concerning both health of its inhabitants, and

ecological stability of the environment. The most often accident of incinerator reported in the last twenty years are, in particular, smaller, as well as very extensive, fires and explosions. Their hazardousness resides especially in the fact that uncontrolled and unregulated burning of the waste mass may take place during them, connected with subsequent uncontrolled release of highly toxic substances into the air. According to the estimates of the United Nations Environment Program (UNEP), up to 1000 micrograms of dioxins (expressed in TEQ) may be released into the air by uncontrolled burning of one ton of waste.

However, uncontrolled releases of toxic substances into the air, caused by poor course of the incineration process, and releases of toxic substances into soil and water during their storage, or during waste handling, are relatively common, too. There may be found many factors causing the accidents: insufficient safety standards, storage of large amount of gases near to incinerators, non-observance of the standards, defects of the equipment, human failures, but also unpredictable coincidences. The most widely encountered hazardous phenomena in the waste sector are fire and the discharge of hazardous or polluting substances. Fire is involved in nearly 80% of all accident occurrences in this sector, which is highly significant. In 45% of the cases, a fire outbreak is combined with the discharge of hazardous or polluting substances. This is especially true for the smoke generated during a fire when hazardous or polluting compounds are present. 22.5% of accidents produce no noteworthy or even known consequences. Should an accident cause damage, in most cases it is mainly economic or environmental in nature. A report from France showed that over half of the accidents caused property damage, and 40 % of accidents release pollution to environment and 1% of cases involving loss of life and slightly above 5% resulting in redundancies.

In general, accident from incinerator would be a risk for institute, therefore in order to prevent the incinerator accident, incinerator operators, and waste handlers, would be trained on safety of incinerator management, and risk management on incubators, and prevention and control measures during accidents. They would be informed of the importance of consistent use of personal protective equipment. Improvement of monitoring system to prevent any accident and put all flammable materials such as gases away from incinerators. Accidental shortage of gas or oil for the incinerator to also poses risks and hence care should be taken in selecting an appropriate fuel tank.

In EPHI, waste are collected from laboratories and they are stored at the area available for collection at temporary storage area near to incinerator and most of the waste would have highly infectious agents that may not be treated at site of generation. If the incinerator is not functional due to different reasons such incinerator failure, absence of operator, shortage of fuel, the waste will be accumulated at central storage, and it will be a risk for EPHI's staff, community and environment. Highly infectious agents will be released to the environment, and large number of people might be infected, resulting life threatening.

Therefore, in order to prevent the accident scenario of incinerator non-functionality, waste will be treated at site of generation and collected in container with lid. Training on health and safety and control measures during incinerator non-function, and the potential risks associated with health-care waste, and rules and procedures required for safe management. In addition, alternatives to incineration such as autoclaving, microwaving and chemical disinfectant which minimize the formation and release of chemicals or hazardous emissions will be used when the incinerator is non-functional as well as we will use Adama central incinerator with safe transport system.

7.3.49.6 Accident of Waste management (central waste storage)

In developing countries, health-care waste has not gained much attention, and the levels of awareness among health care workers of hazards and potential risks of health-care waste are much lower. The impacts of poor health-care waste management differ from one group of workers to another. The staff that cleans the hospital and collects waste may often be at greater risk than a medical staff that produces it. These workers are usually poorly educated and least trained with little attention paid to their safety. Vaccination or proper protective equipment is uncommon for them to have. They can be affected by direct contact with waste every day of their working lives as a result of poor health-care waste management practices.

In the process of health care, waste is generated. Poor management of health-care waste potentially exposes health care workers, waste handlers, patients, and the community to infection, injuries, and toxic pollutants with a great possibility risk for polluting the environment. The impacts of poor health-care waste management differ from one group of workers to another. The staff that cleans the health facilities and collects waste may often be at greater risk than a medical staff that produces it. Health-

care waste handlers can come into contact with medical waste during the process of segregation, collection, transport, storage, and final disposal. They are at greatest risk of infectious hazards, especially when waste that are collected from different facilities at central storage area is not well managed, there is high potential risks for staff, community and environment. The risk of acquiring a secondary infection from a contaminated wastes, sharp depends on the amount of contamination and nature of infection from a source laboratories. The risk of infection with hepatitis B is more than 10 times greater than for hepatitis C, and up to 100 times greater than for human immunodeficiency virus. Other hazards to health-care waste workers include chemical exposures and ergonomic hazards. In addition, mismanagement of health-care waste poses risks to people and the environment (Chartier et al. 2014).

In addition, hazards occur from scavenging at waste disposal sites and during the handling and manual sorting of hazardous waste from health-care facilities. These practices are common in many regions of the world, especially in low- and middle-income countries. The waste handlers are at immediate risk of needle-stick injuries and exposure to toxic or infectious materials.

In EPHI at temporary storage area (near to incinerator), waste are collected from laboratories and they are stored at the area available for collection and most of the waste would have highly infectious agents that may not be treated at site of generation. However when the waste are not properly managed at central storage; they will be a risk for EPHI's staff, community and environment. Highly infectious agents will be released to the environment, and large number of people might be infected, resulting life threatening. In addition scavengers may also come in contact with infectious waste and they can easily transmit the agents to the community and environment.

Therefore in order to prevent the accident, waste handler, and cleaners workers would be trained before starting and on a routine basis to update their knowledge of prevention and control measures. Training in health and safety is intended to ensure that workers know and understand the potential risks associated with health-care waste, and rules and procedures required for safe management. They would be informed of the importance of consistent use of personal protective equipment and would be aware of where to obtain post-exposure follow-up in case of a needle stick injury or other blood exposure.

7.3.49.7 Accident of Waste treatment system failure

Accident scenarios of Wastewater treatment system failure

During the operation of the liquid waste treatment three abnormal scenarios are expected.

1. Optimization of the treatment system during installation
2. Operation failure
3. Lagging of sewerage line construction, that connects the effluent from the treatment to surface water.

If these abnormal events are not properly managed, there would be a health hazard to community. Thus, mitigation measures that involves operation control and alternative disposal measures would be designed.

Operational control:

The operational controls are a set of documented practices, procedures and systems to ensure that the activities of the plant operator which have an impact on the waste water treatment plant performance are carried out in accordance with specified procedures. This would typically be achieved under three sub-sections: control procedures to ensure activities take place within parameter limits; verification, measurement and testing to ensure that the control procedures are effective; and corrective actions to be taken to change the control parameters when failures occur.

During the aforementioned three abnormal scenarios, wastes will be transported using trucks by the Addis Ababa water and sewerage authority (AWSA) to the Kality waste water treatment plant, for a proper treatment and disposal. The treatment plant has the capacity to treat 100,000 m³ of waste water per day. To assist the transportation of the waste to Kality treatment plant a big manhole will be constructed with in EPHI's compound to contain the waste until it is siphoned by the AWSA.

7.3.50 Emergency Preparedness and Response

An emergency is an unexpected event when the BSL 3 laboratory operation loses control, or could lose control, of a situation that may result in risks to human health, property, or the environment, either within the facility or in the local community. Emergencies do not normally include safe work practices for frequent upsets or events that are covered by occupational health and safety. An emergency scenarios usually negative events such as spillage, personnel exposures or contamination (puncture wounds, cuts and abrasions, ingestion of potentially infectious material, potentially infectious aerosol release, broken containers and spilled infectious substances), breakage of tubes containing potentially infectious material in centrifuges, contamination of equipment and facilities, release to the environment (air, water, soil) , equipment failure and natural disasters, are having the

potential to actually increase risk on infectious agents releases from the proposed BSL-3 laboratory. The result of these emergency would be affected the staff, community and environment.

A report from USA revealed that no incidents of infectious materials released from catastrophic accidents at microbiological laboratories. According to the U.S. Army (DA 1989), the likelihood of such catastrophic occurrences is too small to be considered as reasonably foreseeable. No such event has occurred in the more than 50 years in which the military has been conducting biological defence research activities (DA 1989). Moreover, since its inception 78 years ago, EPHI laboratory facilities such as TB and Other Bacterial & Mycotic Diseases, HIV and other viral, Malaria and other parasitic and, Zoonotic diseases, there is no such event has occurred in the history of EPHI laboratories. Thus, the probability of negative event is very low, in addition, if the proposed BSL-3 laboratory would adhere to the application of the WHO laboratory biosafety manual, CDC BMBL Guideline WBG EHS and OSHA and have well established system for emergency preparedness and response or plan the catastrophic of the emergency or events that affecting the health staff and community and environment would be minimal.

Emergency Preparedness and Response plan is of great help to address accident scenarios outlined under subsection 7.3.49. Accident scenarios usually catastrophic events such as earthquake, fire, explosions and airplane crashes, normally considered as initiating events are having the potential to increase risk on microbiological material releases. Emergency Preparedness and Response plan could help to address potential risks/emergencies related to Transportation Accident, Accidents of incinerator, Accident of Waste management (central waste storage), etc.

Therefore, the BSL 3 facility emergency preparedness and response plan would be commensurate with the risks of the facility and that includes the following basic elements:

Administration (policy, purpose, distribution, definitions, etc)

- Organization of emergency areas (command Centres, medical stations, etc)
- Roles and responsibilities
- Communication systems
- Emergency response procedures
- Emergency resources
- Training and updating

- Checklists (role and action list and equipment checklist)
- Business Continuity and Contingency

In addition, an Emergency Preparedness and Response Plan, incorporated into and consistent with, the facility's overall ES/OHS would be prepared to cover the following:

- Planning Coordination: Procedures would be prepared for:
 - Informing the public and emergency response agencies
 - Documenting first aid and emergency medical treatment
 - Taking emergency response actions
 - Reviewing and updating the emergency response plan to reflect changes, and ensuring that employees are informed of such changes
- Emergency Equipment: Procedures would be prepared for using, inspecting, testing, and maintaining the emergency response equipment.
- Training: Employees would be trained on emergency response procedures.
- Include emergency response training details in the comprehensive site work plan.
- Ensure that personal protective equipment (PPE) and other equipment for emergency response in the emergency response plan are identified.
- Site-specific emergency response procedures would be shared to relevant personnel
- Regularly rehearse and training would be provided to employees as part of the overall training program for site operations.

Regarding mitigation to emergency case, the following mitigation measures are tailored specific to the emergency case or an accident scenario as follow:

Mitigation for spillage

The WHO Laboratory Biosafety Manual and WBG EHS Guidelines would be followed for accidents and spillage. So that all staff members will be properly trained and prepared for emergency response including procedures for treatment of injuries, clean-up of the contaminated area, and prompt reporting of all incidents of accidents. All personnel would wearing Personal Protective Equipment (PPE), during clean up or decontamination spill and notify supervisor immediately of any spills that have the potential for serious health or safety implications. The following mitigation actions would be taken (see detail procedure for spill clean-up Annex 9):

- Evacuation of personnel from the contaminated area if required.

- Decontamination or disinfection, rinsing, and wiping dry of the spillage area with an absorbent cloth by personnel wearing adequate protective clothing.
- Decontamination or disinfection of the protective clothing if necessary.
- Accident will be reported to the infection control officer/staff or to HCWM committee if available.
- All cases will be registered by the management team of the HCF and annually reported to the district health authorities.

All personnel would perform blood tests following such an injury to ensure that the injured staff has not been contaminated by pathogens like HIV, HBV, and HCV according to Ethiopia Post exposure prophylaxis (PEP) policy and guidelines. The BSL 3 laboratory would maintain a written procedure accessible to staff that includes procedures for each type of spill that could be expected in the facility to help guide appropriate response.

Mitigation for Personnel Exposures or Contamination

- Remove the exposed or contaminated personnel from the contaminated area, unless it is unsafe to do so due to the medical condition of the victim or potential hazard to the rescuer
- If the incident occurs during normal working hours, notify Medical Centre
- Administer first aid as appropriate
- Remove any contaminated clothing
- Proceed to the nearest emergency eyewash/shower to flush contamination from the eyes and skin
- Stand by to provide emergency information.

The common expected personnel incident in BSL 3 laboratory with mitigation measures described as follow:

Puncture wounds, cuts and abrasions: The affected individual would remove protective clothing, wash the hands and any affected area(s), apply an appropriate skin disinfectant, and seek medical attention as necessary. The cause of the wound and the organisms involved would be reported, and appropriate and complete medical records kept.

Ingestion of potentially infectious material: Protective clothing would be removed, and medical attention sought. Identification of the material ingested, and circumstances of the incident would be reported, and appropriate and complete medical records kept.

Potentially infectious aerosol release: All persons would immediately vacate the affected area and any exposed persons would be referred for medical advice. The laboratory supervisor and the biosafety officer would be informed at once. No one would enter the room for an appropriate amount of time (e.g. 1 h), to allow aerosols to be carried away and heavier particles to settle. If the laboratory does not have a central air exhaust system, entrance would be delayed (e.g. for 24 h). Signs would be posted indicating that entry is forbidden. After the appropriate time, decontamination would proceed, supervised by the biosafety officer. Appropriate protective clothing and respiratory protection would be worn.

Broken containers and spilled infectious substances: Broken containers contaminated with infectious substances and spilled infectious substances would be covered with a cloth or paper towels. Disinfectant would then be poured over these and left for the appropriate amount of time. The cloth or paper towels and the broken material can then be cleared away; glass fragments would be handled with forceps. The contaminated area would then be swabbed with disinfectant. If dustpans are used to clear away the broken material, they would be autoclaved or placed in an effective disinfectant. Cloths, paper towels and swabs used for cleaning up would be placed in a contaminated-waste container. Gloves would be worn for all these procedures. If laboratory forms or other printed or written matter are contaminated, the information would be copied onto another form and the original discarded into the contaminated-waste container.

Breakage of tubes containing potentially infectious material in centrifuges: If a breakage occurs or is suspected while the machine is running, the motor would be switched off and the machine left closed (e.g. for 30 min) to allow settling. If a breakage is discovered after the machine has stopped, the lid would be replaced immediately and left closed (e.g. for 30 min). In both instances, the biosafety officer would be informed. Strong (e.g. thick rubber) gloves, covered if necessary with suitable disposable gloves, would be worn for all subsequent operations. Forceps, or cotton held in the forceps, would be used to retrieve glass debris. All broken tubes, glass fragments, buckets, trunnions and the rotor would be placed in a noncorrosive disinfectant known to be active against the organisms

concerned. Unbroken, capped tubes may be placed in disinfectant in a separate container and recovered. The centrifuge bowl would be swabbed with the same disinfectant, at the appropriate dilution, and then swabbed again, washed with water and dried. All materials used in the clean-up would be treated as infectious waste.

Mitigation for Contamination of Equipment and Facilities

- Do not attempt any clean-up or decontamination procedures alone or without wearing Personal Protective Equipment (PPE), including respiratory protection if respiratory pathogens may be present. Unless the spill is minor and well defined do not clean up the material without approval.
- Avoid spreading contamination by limiting access to the contaminated equipment or area only to individuals who are properly protected and trained to respond to all types of hazards that exist (e.g., biological, radioactive, and chemical).
- Report details the incident and request assistance.
- If the spill involves a liquid, place absorbent material on the spill and decontaminate with an approved disinfectant for a minimum of a 30-minute contact time.
- If sharps are involved, pickup using a mechanical means, such as tongs, forceps, or dustpan and broom. Do not use your hands to pick up any sharp items, even if gloves are worn.
- Decontaminate the equipment and area using appropriate methods.
- Stand by to provide emergency information and assistance to Emergency Response Personnel.

Mitigation for Release to the Environment (air, water, soil)

- Stop the release, if safe to do so.
- Follow procedures described above mitigation for contamination of equipment and facility.
- Make immediate notifications.

Mitigation for Equipment Failure

If the autoclave equipment fails, medical waste would be handled by one of the following methods:

- If there is another option, the medical waste can be autoclaved/decontaminated by other methods
- Medical waste can be stored at temperatures greater than 32 °F (0°C) for up to 7 days prior to treatment.

- The medical waste may also be stored frozen for up to 90 days. Attempts will be made to complete repair within this time.

Mitigation for Natural Disasters

In the event of a natural disaster, all generating medical waste will be suspended until adequate medical waste treatment becomes available. In the event of a spill, the medical material will be disinfected using 10% bleach solution or another approved disinfectant for a 30-minute contact time and cleaned. Response to significant spills or releases of medical agents will be coordinated with safety officer. Personnel performing disinfection procedures shall be equipped with the appropriate personal protective equipment (PPE) for the situation, but at a minimum shall wear chemical eye protection and latex gloves. Protective clothing, shoes, and a face shield may be required for large quantities of medical materials. In addition please follow procedures described for Laboratory Release Accident Scenario.

8 Environmental and social management plan (ESMP)

This chapter addresses institutional responsibilities for implementation of activities proposed for management of environmental and social risks, environmental monitoring, capacity development and training, and Chance Finds and GRM Procedure. A standalone Infection Control and Waste Management Plan (ICWMP) has been prepared which will also help to address environmental and social risks associated with the BSL3 NRL complex.

8.1 Institutional arrangement, roles and responsibilities for ESMP implementation

Institutional responsibility of implementing this ESMP will rest with the Project Coordination Team, under Public Health Infrastructure Directorate (PHID) at FMOH. A key role of the unit would be among others, to review consultants' reports for compliance with the ESMP. Other roles will be:

- Monitoring implementation of mitigation actions by contractors
- Coordinating and providing training and capacity building where planned
- Periodically report to FMOH about implementation of the ESMP

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

- Prepare plans for effective project development and management;
- Co-ordinate the project programs and actions plan, and the various sub-project safeguard activities;
- Manages ACRIFP project construction contracts and supervises project sights;
- Ensure that the design of all ACRIFP laboratories incorporate provision for addressing environmental impacts, 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.

The Project Coordination Team is led by a team leader, and focal persons who have supervisory roles and are responsible for collecting information about respective components. Supervision of the implementation of this ESMP will be under the Public Health Infrastructure component. MOH

should ensure that all its personnel to be involved in the implementation of this ESMP are adequately qualified and were appointed based on their qualification and suitability for respective roles. There is thus no training provided for them under this ESMP.

Oversight to ensure mitigation actions are implemented will rest with the Public Health Infrastructure Directorate (HID) at Ministry of Health but health workers at facility level, Project Coordination Unit, In-charge Officials of each facilities and Work supervisor will have similar responsibility. MOH shall require contractors to comply with this ESMP and where a contractor has an Environmental Officer he /she will undertake environmental supervision during construction. It is believed that the project proponent in this case, the PHID, Project Coordination Team (PCT), the construction supervisor and the Addis Ababa Administration officers responsible for environment will take the major responsibility in supervising the implementation of the environmental mitigation and monitoring plans.

For mitigation measures related to design change, the engineering consultancy organization assigned to design the proposed development project will be responsible for incorporating the recommended mitigation measures into the design and into the technical specifications of the main project report.

During construction, the contractor will be responsible for implementing environmental mitigation measures included in the present ESIA report. The construction supervisor and delegated officers from the PHID and PCT will monitor the proper implementation of mitigating measures at the right time. The Contractor will be fully responsible for ensuring that all the work will be carried out as per the environmental requirements indicated in the design and technical specifications and the present ESIA report.

It is also envisaged that an environmentalist would be intermittently assigned by Addis Ababa AEPA to monitor implementation of the mitigating measures. The delegated staffs from the PHID and PCT and the construction supervisor's environmentalist will be jointly responsible for the overall coordination of the environmental management activities. They will advise the contractors, construction supervisors, the project management unit of the PHID/PCT and the relevant authorities regarding the implementation of the environmental mitigating measures and monitoring of impacts.

During the operation period, the environmental issues will be monitored jointly by Addis Ababa Environmental Forest Climate Change Commission (AAEFCC) or its counterpart sub-city office, Woreda (such as Woreda 9), and the EPHI. The Management of the BSL 3 NRL Project may also organize a unit for Environment, Health and Safety to enable implementation and monitoring of the mitigation measures during operational phases. In addition, AAWSSA will also involve in wastewater and solid waste disposal.

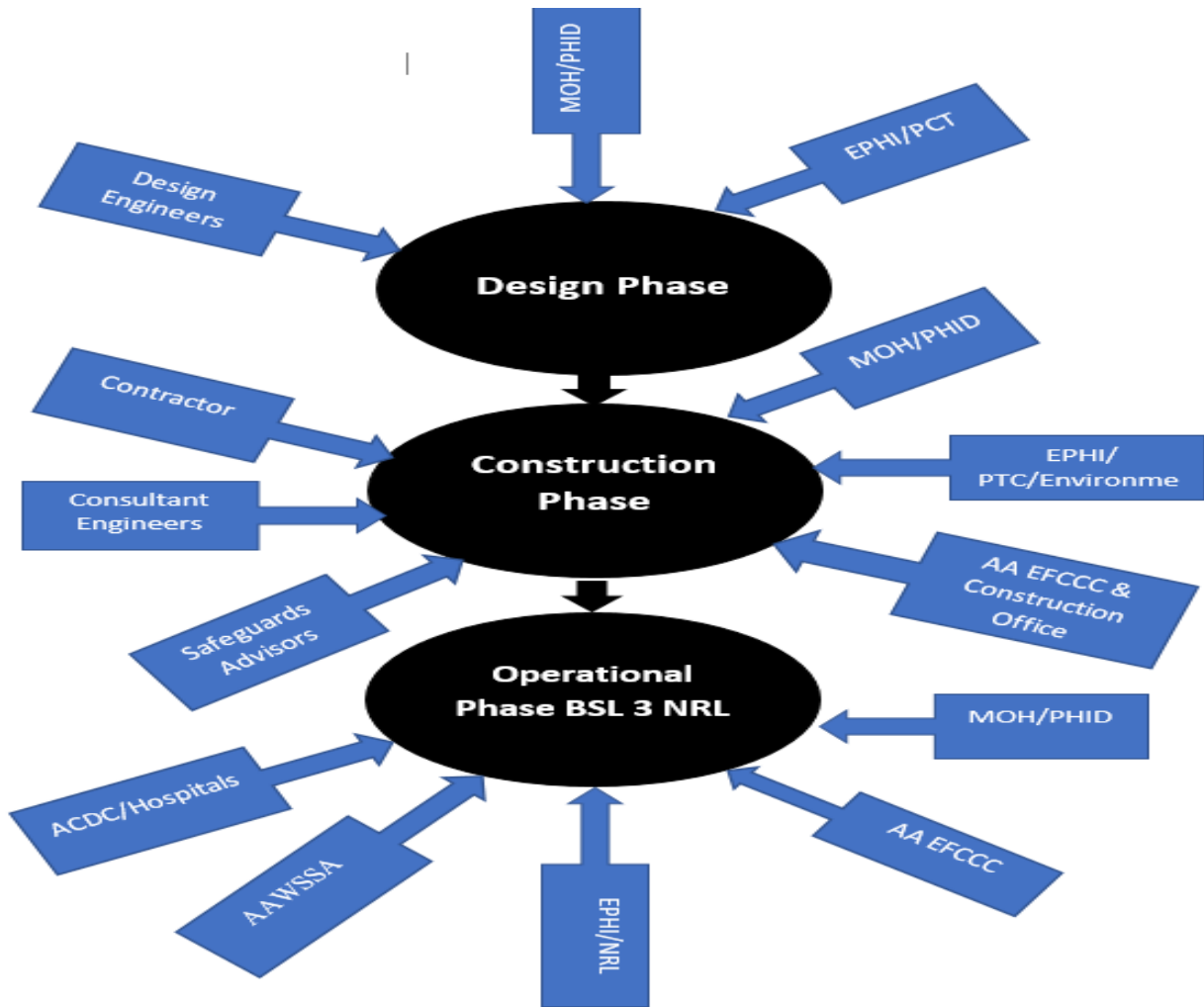


Figure 17: Schematic diagram that shows the stakeholders at design, construction and operational phase

The EHPI will have a biosafety and security unit to address and comply with regulations and recommendations for biosafety and biosecurity, and as well as the health and safety of the staff, researchers, community, and environment. EPHI will be responsible for overall management of the proposed BSL3 lab. To maintain regulatory compliance and to protect personnel, the

community and the environment from biohazards, EPHI will be responsible for appointing laboratory director, biosafety and biosecurity officer and other technical and support staff required for the BSL-3 lab; ensuring appropriate training is provided to personnel conducting research with biohazards or recombinant or synthetic nucleic acid materials; ensuring that research conforms to the provisions of best international practices such as the *NIH Guidelines*, *BMBL*, *WHO Biosafety Manual* and *this ESIA*; establishing and maintaining a *Biosafety Committee*; establishing and maintaining a health surveillance program for personnel; reporting, when required, any significant problems, violations or significant research-related accidents or illnesses to pertinent Ethiopian Public Health and Environmental issues regulatory organs; and facilitating the preparation of guidelines, policies and plan relevant for smooth functioning of the lab.

The BSL-3 facility will employ the following on a full-time bases, but not limited to except for the laboratory manager, the number of personnel will be determined based on the work load. The staff to be deployed include laboratory director, laboratory scientist, laboratory quality Manager, biosafety and biosecurity officer, HVAC technician, electrical technician, equipment and instrument maintenance technician, security staff, incinerator operator, cleaners, wastewater treatment plant operator. These staff will help to ensure proper implementation of the ESMP and ICWMP; and their roles and responsibilities are described in section 2.

8.2 Mitigation Measures Plan

The mitigation measures for anticipated environmental and social risks from the proposed BSL3 lab complex is outlined in Table 17.

Table 17: Environmental and Social risks mitigation measures plan (Also note that a standalone infection control and waste management plan has been prepared for the BSL3 lab based on this plan)

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
Pre-construction phase				
Design fault	Improve and approved design against WBG EHS guideline for facility design, WHO Laboratory safety manual.	Consultants/ MOH/EPHI	Before construction	10,000.00
Construction phase				
Positive impact				
1. Income to construction material suppliers and contractors	<ul style="list-style-type: none"> - The project will promote in country procurement where technically or commercially reasonable and feasible. - For earth materials, procure from legitimate sources to avoid encouraging environmental degradation 	<ul style="list-style-type: none"> - Construction contractor - Construction supervisor 	During Construction Phase	Budget included in project cost
2. Employment Opportunities	<ul style="list-style-type: none"> - Labor will be recruited exclusively from local community, and professionals will be recruited preferentially from such communities, provided that they have the requisite qualification, competence and desired experience. - Contractors will be required to pay a “living wage” to all workers. 	<ul style="list-style-type: none"> - Construction contractor - Construction supervisor 	During Construction Phase	Budget included in project cost
Negative impact				
1. Impacts on Ecological Resources and Biodiversity	Limit extent of vegetation and tree clearing			

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	Replant and re vegetation clearing/Re-vegetating areas promptly			
2. Impact on Geology/Soils	Soil erosion prevention measures would be in place during the construction phase to minimize erosion from storm water; Dust suppression measures would be employed to minimize wind erosion.			
3. Impact of improper construction and demolition waste management	<ul style="list-style-type: none"> - The wastes will be properly segregated and separated to encourage recycling of some useful waste materials, - The contractor and EPHI administration will work together with the Municipal Council to facilitate proper waste handling and disposal from the site. All wastes must be taken to the approved dumpsites. - Hazardous waste will not be mixed with other solid waste generated and would be managed by way of incineration or land-filling. - Waste will be picked off the site every day and when temporarily kept on site it will be covered to minimize nuisance odour and vermin 	<ul style="list-style-type: none"> - Construction Contractor - Construction supervisor - PCT 	During Construction Phase	2,000.00
4. Impacts from physical hazards	<ul style="list-style-type: none"> - Orientation would be provided to all construction workers on safe work practices and guidelines and ensure that they adhere to them. - Training on incidences handling and prevention would be provided to workers. This would involve proper handling of electricity, water etc. and orientation on various modes of escape, conduct and responsibility during such incidences. All workers must fully be aware for potential emergency. 	<ul style="list-style-type: none"> - Construction Contractor - Construction supervisor 	During Construction Phase	7,000.00

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> - 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 of signage to warn staff and/ or visitors that are not involved in construction activities of dangerous places. - Safety supervision of works would be done regularly to ensure that safety conditions are met while any deviation from safety regulations is immediately reclaimed following the best practices regarding safety at work equipment. - Develop evacuation procedures to handle emergency situations. - Provide appropriate personnel protective equipment (PPE) to all workers. 			
5. Impact from Electrical and Explosive Hazards	<ul style="list-style-type: none"> - All electrical installations and equipment would be inspected and tested regularly, including earthing/grounding systems. - Specialized refrigerators would be used when storing chemicals that have explosion potential. 	- Construction Contractor	During Construction Phase	1,000.00
6. Impact from traffic accidents	<ul style="list-style-type: none"> - Adopt best transport safety practices with the goal of preventing traffic accidents and minimizing injuries suffered by project personnel and the public - Ensure drivers respect speed limits through built up areas and urban Centres. - Ensure that vehicles are regularly maintained to minimize potentially serious accidents such as those caused by brake failure commonly associated with loaded construction trucks 	- Construction Contractor	During Construction Phase	8,000.00

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> - Employ safe traffic control measures, including temporary road signs and flag persons to warn of dangerous conditions and children crossings 			
7. Impact on Air quality	<ul style="list-style-type: none"> - Contractors would use dust screens or nets in windows, doorways and ventilators of rooms where demolition or other dusty construction activities are occurring. - Ensure good housekeeping and clean construction operations where, among other necessary actions, dust would be quickly swept off cement floors and collected in covered containers. - EPHI administrator would have authority to inspect and restrain contractors from generating excessive dust within institute environment - To minimize indoor dust, portable extraction systems are recommended but they might not be available among local contractors, or lack of electricity on site might limit their use. Water sprays are not practical and could lead to indoor flooding of surrounding rooms or service areas occupied by patients. - Trucks would be covered during haulage of construction materials and would be diverted away from sensitive areas of the institute. 	<ul style="list-style-type: none"> - Construction Contractor 	During Construction Phase	Budget included in project cost

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
8. Impact of noise and vibrations	<ul style="list-style-type: none"> - Construction workers will be aware of the sensitive nature of workplaces they are operating in and advised to limit verbal noise or other forms of noise. For example, metallic objects or tools can be passed on to a colleague rather than dropping or throwing them with loud bangs. - Contractor will be careful when selecting equipment to avoid use of old or damaged machinery with high level of noise emissions that would have a negative impact in the environment. - All heavy duty immovable equipment will be fitted with mufflers or placed in enclosures to minimize disrupting ambient noise levels - Contractor will ensure that equipment is properly maintained and fitted with mufflers. - Where possible, contractors would cordon off areas under construction with noise absorbing materials, for example, plywood rather than iron sheets. - The contractor would ensure that noise levels emanating from machinery, vehicles and noisy construction activities are kept at a minimum for the safety, health and protection of people in the nearby buildings. - Construction workers and drivers would be sensitized to switch off Equipment, machinery and vehicle engines when not in use and/or offloading materials. 	<ul style="list-style-type: none"> - Construction Contractor 	During Construction Phase	Budget included in project cost

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> - Construction activities would be carried out during the day time 			
9. Impact on social service caused by disruption of laboratory/ Sample collection services	<ul style="list-style-type: none"> - Plan pre-construction activities early to identify suitable rooms or adjoining buildings into which the sample collection can be carried out with minimal inconvenience 	Construction Contractor Construction supervisor PCT	During Construction Phase	Budget included in project cost
10. Risk associated with the existing incinerators	<ul style="list-style-type: none"> - maintain the incinerators periodically 	- EPHI	During the construction phase	1,500
11. Risks associated with the demolition and disposal of existing incinerators (This ESIA will be updated to cover risks associated with the demolition/decommissioning of the existing incinerators)				Total cost 5000

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
<p>11.1 Release of residue ash</p> <p>Potential chemical wastes to be generated from the decommissioning and demolition of the incinerators associated ductworks include residual ash. The key environmental impacts are associated with the residual ash remaining in the incinerator unit and ash collector</p>	<ul style="list-style-type: none"> The decommissioning and demolition work will be carried out in full containment, a decommissioning company will be employed with adequate health and safety protection measures in place. A suitably licensed waste collector will be used to collect, transport and dispose the chemical wastes to the designated treatment facility 	EPHI, the Decommissioning Company	Before the BSL3 NRL complex becomes operational	Cost included in the total decommissioning cost
<p>11.2 Dust</p>	<ul style="list-style-type: none"> Wet wiping of the surface to minimize airborne dust. The decommissioning and demolition work will be carried out in full containment. 	EPHI, the Decommissioning Company	Before the BSL3 NRL complex becomes operational	Cost included in the total decommissioning cost
<p>11.3 Release of asbestos containing materials and chemical waste</p> <p>A list of substances or chemicals (in any form, quantity and concentration), including asbestos, dioxins, polychlorinated biphenyls (PCBs) and heavy metals (HMs) would cause pollution or constitute a danger to health or risk of pollution to the environment.</p>	<ul style="list-style-type: none"> The decommissioning and demolition work will be carried out in full containment, a decommissioning company will be employed with adequate health and safety protection measures in place. Appropriate waste collection procedure will be used to collect, transport and dispose the chemical wastes to the designated treatment facility. 	EPHI, the Decommissioning Company	Before the BSL3 NRL complex becomes operational	Cost included in the total decommissioning cost
<p>11.4 Wastewater</p>	<ul style="list-style-type: none"> The floor drain in the incinerator room will be covered with a temporary seal during the decommissioning and demolition works. The top of the chimney would be sealed with polyethylene sheets at least twenty-four (24) hours before the works commence. 	EPHI, the Decommissioning Company	Before the BSL3 NRL complex becomes operational	Cost included in the total decommissioning cost

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
12. Emergency Preparedness and Response	<ul style="list-style-type: none"> - Organization of emergency areas - Communication systems - Emergency response procedures - Training and updating - Checklists (role and action list and equipment checklist) - Business Continuity and Contingency 			2,500
Operation phase *				
Positive impact				
1. Improved medical surveillance services	- Construction of BSL 3 laboratory, would be matched with commensurate staffing with laboratory/ biomedical engineering personnel adequately trained in use of newly installed equipment	- EPHI and FMoH	During Operation Phase	12,000.00
2. Generation of additional permanent employment	- Operation of the BSL 3 laboratory facility will create additional permanent technical and non-technical job opportunities for laboratory, biomedical engineering professionals, and other supportive personnel.	- EPHI and FMoH	During Operation Phase	72,000.00 per annum
Negative Impact				
1. Impacts on Ecological Resources and Biodiversity	- Personnel working on the BSL 3 NRL complex would be trained on emergency preparedness and responses	BSL 3 NRL Administration EPHI Management and HSE Officer	During Operation Phase	1,000

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
2. Impacts from physical hazards	<ul style="list-style-type: none"> - All workers to be provided with appropriate PPE against exposure to infectious pathogens, hazardous chemicals and ionizing radiation in accordance with recognized international safety standards and guidelines. - Orientation for all staff would be given on safe work practices and guidelines and ensure that they adhere to it. - Training would be conducted on incident handling and prevent manage. This would involve proper handling of electricity, water etc. and sensitization on various modes of escape, conduct and responsibility during such incidences. - 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. 	<p>BSL 3 NRL Administration</p> <p>EPHI Management and HSE Officer</p>	During Operation Phase	10,000.00 Per annum.
3. Impact from Electrical and Explosive Hazards	<ul style="list-style-type: none"> • All electrical installations and equipment would be inspected and tested regularly, including earthing/grounding systems. • Circuit-breakers and earth-fault-interrupters would be installed • All laboratory electrical equipment would be earthed/grounded, Disconnect equipment attached to high-voltage or high-amperage power sources 	<p>BSL-3 NRL Administration.</p> <p>EPHI</p>	During Operation phase	Budget included the construction

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> Never place flammable liquids in a household refrigerator. 			
4. Impact from Chemical Hazard	<ul style="list-style-type: none"> Only small amounts of chemicals necessary for daily use would be stored in the laboratory. Replacement of the hazardous substance with a less hazardous substitute Implementation of engineering and administrative control measures to avoid or minimize the level of exposure below internationally established or recognized limits Where corrosive, oxidizing, or reactive chemicals are used, handled, or stored, qualified first-aid would always be ensured. Appropriately equipped first-aid stations would be easily accessible throughout the place of work, and eye-wash stations and/or emergency showers would be provided close to all workstations where the recommended first-aid response is immediate flushing with water Material 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 	<ul style="list-style-type: none"> BSL-3 NRL Administration. EPHI 	During Operation phase	45,000.00
5. Impact of escaping of Infectious Agents from BSL 3 labs, PTPC and Biobank centre	<ul style="list-style-type: none"> Personnel working in BSL 3 lab, PTPC and biobank would be trained on sample and waste handling, transportation, and storage Equipment would be maintained and calibrated periodically 	<ul style="list-style-type: none"> BSL-3 NRL Administration. EPHI 	During Operation phase	1,000.00

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> BSCs HEPA filters would be tested annually and replaced as necessary. Effective vaccines or therapeutic measures would be available for all risk groups All material would be sterilized by autoclave or chemical disinfection BSL 3 lab, PTPC and Biobank would be locked always, and access restricted for non-authorized personnel All agents would be contained within the laboratory and biosecurity system would be in place. 			
6. Potential Occupational Health and safety impacts associated with BSL 3 Laboratory operation	<ul style="list-style-type: none"> Implement the facility containment devices, and administrative controls BSL-3 Good Microbiological Practices for the BSL 3 Laboratory Implement special practices for BSL 3 laboratory Use Personal Protective Equipment during performing activities in BSL 3 Laboratories Use laboratory Secondary Barriers for BSL 3laboratory Check HEPAs periodically 	<ul style="list-style-type: none"> - BSL-3 NRL Administration. - EPHI 	During Operation phase	10,000.00
7. Potential impacts associated with operation of BSL 2 laboratories, PTPC and Biobank	<ul style="list-style-type: none"> All procedures involving the manipulation of infectious materials would be conducted within BSCs or other physical containment devices and PTPC and Biobank centre would have special engineering and design features. Personnel working in PTPC and Biobank centre 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 	<ul style="list-style-type: none"> - BSL-3 NRL Administration. - EPHI 	During Operation phase	2 500

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
8. Impact of handling of infectious materials and specimens in the proposed BSL 3 laboratory	<ul style="list-style-type: none"> • Use robust and leak-proof specimen containers • Personnel would be trained on specimen and waste handling, transport and storage. • Use triple package during transportation of infectious materials • Follow working procedure during handling package during transportation of infectious materials 	<ul style="list-style-type: none"> - BSL-3 NRL Administration. - EPHI 	During Operation phase	2,000.00
9. Impact of handling and storage of infectious materials and specimens in the proposed BSL 2 laboratories, PTPC and Biobank	<ul style="list-style-type: none"> • Use robust and leak-proof specimen containers • Containers would be correctly labelled to facilitate identification. • Specimen request or specification forms would not be wrapped around the containers but placed in separate, preferably waterproof envelopes. • Secondary containers, such as boxes, would be used, fitted with racks so that the specimen containers remain upright. 	<ul style="list-style-type: none"> - BSL-3 NRL Administration. - EPHI 	During Operation phase	2,500
10. Impact associated with the use of equipment in the BSL 3 laboratory	<ul style="list-style-type: none"> • Training of workers in equipment operating and handling techniques during operation. • Periodic maintenance and calibration of equipment according to manufacture recommendation. • Operation of equipment according to the manufacturer's instructions 	<ul style="list-style-type: none"> - BSL-3 NRL Administration. - EPHI 	During Operation phase	1,000.00
11. Impact of improper use of equipment in the BSL 2 labs, PTPC and Biobank	<ul style="list-style-type: none"> • Training of workers in equipment operating and handling techniques during operation. • Periodic maintenance and calibration of equipment according to manufacture recommendation. • Operation of equipment according to the manufacturer's instructions. 	<ul style="list-style-type: none"> - BSL-3 NRL Administration. - EPHI 	During Operation phase	

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
12. Impact of contamination of the BSL 3 laboratory, BSL 2 laboratories, PTPC and Biobank Facilities	<ul style="list-style-type: none"> • Workers would be trained on evacuation of the contaminated area • Workers would also be trained on decontamination or disinfection, • Rinsing, and wiping dry of the spillage area with an absorbent cloth by personnel wearing adequate protective clothing and • Decontamination or disinfection of the protective clothing if necessary. • Handling and managing of spill and splash 	<ul style="list-style-type: none"> - BSL-3 NRL Administration. - EPHI 	During Operation phase	1,000.00
13. Potential impact during the operation of central Warehouse	<ul style="list-style-type: none"> ○ Replacement of the hazardous substance with a less hazardous substitute ○ Implementation of engineering and administrative control measures ○ Appropriately first-aid stations would be easily accessible to all workstations ○ Keeping the number of employees exposed, or likely to become exposed, to a minimum ○ Communicating chemical hazards to workers through labelling and marking ○ Material Safety Data Sheets (MSDS), would be in an easily understood language and be readily available ○ Training workers in the use of MSDSs, safe work practices, and appropriate use of PPE ○ Store chemicals in a well-ventilated area; however, do not store chemicals in a fume hood. ○ Maintain an inventory of all chemicals in storage. 	<ul style="list-style-type: none"> - BSL 3 NRL Administration - EPHI 	During Operation Phases	5,000.00 per annum

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> ○ Return chemical containers to their proper storage location after use. ○ Store glass chemical containers so that they are unlikely to be broken. ○ Store all hazardous chemicals below eye level. ○ Never store hazardous chemicals in a public area or corridor. ○ Separate acids from bases. Store these chemicals near floor level. ○ Isolate perchloric acid from organic materials. Do not store perchloric acid on a wooden shelf. ○ Separate highly toxic chemicals and carcinogens from all other chemicals. This storage location should have a warning label and should be locked. ○ Separate acids from flammables. ○ Not keep peroxide-forming chemicals longer than twelve months. ○ Not allow picric acid to dry out. ○ If flammables need to be chilled, store them in a laboratory-safe refrigerator, not in a standard refrigerator. ○ Flammables would be stored in a flammable storage cabinet. ○ Store reactive materials separate from corrosives or flammables. ○ Store Nitric acid (reactive and corrosive) separately from other acids and flammables. ○ Storage location would clearly indicate which group/code is stored in that location. Each shelf or cabinet should indicate the colour. 			

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> ○ Groups would always be separated by a vertical divider not horizontal divider. ○ Each chemical container would be clearly labelled by its storage colour 			
14. Impact of fire outbreak	<ul style="list-style-type: none"> ○ All staff will have training in fire control through ○ Regular firefighting drills. ○ Fire extinguishers would be available in accessible area and ensure that all fire-fighting equipment is regularly maintained and serviced. ○ Fire emergency telephone numbers would be displayed in communal areas. ○ Automatic fire alarm system for the entire laboratory will be installed. ○ Fire suppression for the BSL-3 facility would be provided by a standard wet-pipe fire sprinkler system. ○ Fire hazard signs such as ‘No Smoking’ signs will be provided. ○ Directions to exit in case of any fire incidence and emergency contact numbers will be provided. ○ The contact/emergency numbers will be displayed within the laboratory. ○ All staff will have training in fire control through regular firefighting drills. 	-		
15. Chemical Hazard in the BSL 3 NRL Complex Building	<ul style="list-style-type: none"> ● Only small amounts of chemicals necessary for daily use would be stored in the laboratory. ● Replacement of the hazardous substance with a less hazardous substitute ● Implementation of engineering and administrative control measures 	<ul style="list-style-type: none"> - BSL-3 NRL Administration. - EPHI 	During operation phase	45,000.00

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> • Appropriately equipped first-aid stations would be easily accessible throughout the laboratory workstations • Communicating chemical hazards to workers through labelling and marking according to national and internationally recognized requirements and standards, • Material Safety Data Sheets (MSDS) would be in an easily understood language and be readily available to laboratory personnel • Training workers in the use of the MSDSs, safe work practices, and appropriate use of PPE 			
16. Electrical and Explosive Hazards in the BSL 3 NRL Complex Building	<ul style="list-style-type: none"> • All electrical installations and equipment are inspected and tested regularly. • Circuit-breakers and earth-fault-interrupters would be installed in appropriate laboratory electrical circuits. • All laboratory electrical equipment would be earthed/grounded, preferably through three-prong plugs. • All laboratory electrical equipment and wiring would conform to national electrical safety standards and codes 	<ul style="list-style-type: none"> - BSL-3 NRL Administration. - EPHI 	During Operation phase	Budget included the construction
17. Ergonomic Hazards in the BSL 3 NRL Complex Building	<ul style="list-style-type: none"> • Training of workers in lifting and materials handling techniques during operation, • Planning work site layout to minimize the need for manual transfer of heavy loads • Selecting tools and designing work stations that reduce force requirements and holding times 	<ul style="list-style-type: none"> - BSL-3 NRL Administration. - EPHI 	During Operation phase	1,000
18. Impact of Air pollution due to waste incineration	<ul style="list-style-type: none"> • Waste segregation for wastes with polychlorinated would be done and these wastes would never be incinerated, 			5,000

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> Materials free of polychlorinated 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 incinerators periodically Purchase new environmentally friendly incinerator see annex 7 for specifications 	<ul style="list-style-type: none"> BSL-3 NRL Administration. EPHI Supplier of the incinerator 	During Operation phase	
19. Noise and Vibration	<ul style="list-style-type: none"> All generators and laboratory equipment will be insulated or placed in enclosures to minimize disrupting ambient noise levels. 	<ul style="list-style-type: none"> BSL-3 NRL Administration. 	During Operation phase	-
20. Misuse and/or theft Agents and laboratory equipment/supplies in the BSL 3 NRL Complex Building	<ul style="list-style-type: none"> Strict Biosecurity measures would be implemented to limit access to facilities, research materials and information. Continue the use of digital inventory system for both the microorganisms and equipment. Develop measures to protect against the insider threat (employees, staff, or contractors), or outsider threat (outsiders who intend to gain access to do harm) and any natural or manmade events that could cause a release. Establish system for physical security, personnel security, material control & accountability, and information security All staff will have training in laboratory security and biosecurity. 	<ul style="list-style-type: none"> BSL 3 NRL Administration EPHI 	During Operation Phase	1,500.00

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> All BSL 3 labs, BSL2 labs, Biobank and PTPC would be lock always and non-authorized personnel forbidden to enter the facilities without permission. 			
21. Gender Based Violence Impacts	<ul style="list-style-type: none"> Conduct continued sensitization and awareness raising to EPHI staff in general and BSL-3 NRL staff in particular on prevention of GBV. Strengthen the Gender and women office of EPHI to address GBV cases when it occurs. 	<ul style="list-style-type: none"> BSL 3 NRL Administration EPHI women and youth office 	During Operation Phase	2,500
22. Impact due to Improper Waste Management	<ul style="list-style-type: none"> Develop and implement a waste management plan for EPHI in general and for the proposed NRL project Initial packaging and storage would take place where HCW is generated. Storage of waste will then be moved to a temporary on-site storage location Non-risk HCW would always be stored in a separate location from the infectious/ hazardous HCW in order to avoid cross-contamination. Strengthen the internal waste management system (collection, storage and disposal) of the EPHI and equip it with additional facilities to allow for segregated collection at source. All sharps used in the BSL-3 would be autoclaved prior to incineration. Sharps would be placed in rigid, puncture-resistant containers made of glass, metal, rigid plastic, or cardboard. 	<ul style="list-style-type: none"> BSL 3 NRL Administration EPHI 	During Operation Phase	870, 000

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> • 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. • Solid waste generated in the BSL-3 laboratory would leave the laboratories only after decontamination using the laboratory's autoclave. • Non-hazardous wastes that are generated by the BSL-3 would be incinerated. • Liquid Waste discharged from laboratory would be treated chemically prior to being released to the waste tank. • Liquid waste treatment plan would be constructed at EPHI to improve the capacity of the tank. • Provide appropriate waste bins (colour coded) for the different types of waste generated in the BSL 3 NRL to allow segregation and collection at the point of generation. • Laboratory staff and all other staff involved in waste handling would be trained on the waste handling treatment, and disposal techniques. 			

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> Fumigation of the laboratory by disinfectant gases would be conducted according to WHO laboratory manual. Regular visual inspection of all waste storage collection and storage areas for evidence of accidental releases and to verify that wastes are properly labelled and stored. Regular audits of waste segregation and collection practices. Tracking of waste generation trends by type and amount of waste generated, preferably by facility departments. Keeping manifests or other records that document the amount of waste generated and its destination. 			
23. Impact associated with collection/ handling and storage of waste at BSL 3 Lab complex building	<ul style="list-style-type: none"> Develop and implement a waste management plan for EPHI in general and for the proposed NRL project Initial packaging and storage would take place where HCW is generated. Storage of waste will then be moved to a temporary on-site storage location Non-risk HCW would always be stored in a separate location from the infectious/ hazardous HCW in order to avoid cross-contamination. Strengthen the internal waste management system (collection, storage and disposal) of the EPHI and equip it with additional facilities to allow for segregated collection at source. All sharps used in the BSL-3 would be autoclaved prior to incineration. Sharps would be placed in rigid, puncture-resistant containers made of glass, metal, rigid plastic, or cardboard. 	<ul style="list-style-type: none"> - BSL 3 NRL Administration - EPHI 	During Operation Phase	25, 000

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> • 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. • Solid waste generated in the BSL-3 laboratory would leave the laboratories only after decontamination using laboratory's autoclave. • Non-hazardous wastes that are generated by the BSL-3 would be incinerated. • Liquid Waste discharged from laboratory would be treated chemically prior to being released to the waste tank. • Liquid waste treatment plant would be constructed at EPHI to improve the capacity of the tank. • Laboratory staff and all other staff involved in waste handling would be trained on the waste handling treatment, and disposal techniques. • Fumigation of the laboratory by disinfectant gases would be conducted according to WHO laboratory manual. • Regular visual inspection of all waste storage collection and storage areas for evidence of accidental releases and to verify that wastes are properly labelled and stored. • Regular audits of waste segregation and collection practices. • Tracking of waste generation trends by type and amount of waste generated, preferably by facility departments. 			

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> Keeping manifests or other records that document the amount of waste generated and its destination. 			
<p>24. Risks associated with waste transportation within EPHI campus</p>	<ul style="list-style-type: none"> Set routes would be used to prevent exposure to staff and patients All waste bags would in-place and intact at the end of transportation Carts, trolley, or containers used for the transportation of infectious waste would not be used for the transportation of any other material A trolley, bin, or wheelbarrow will be used for transporting safety boxes and bins. Waste that has the potential to leak will 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 The collected waste will not be left even temporarily anywhere other than at the designated storage room. Containers would be covered with lids during storage and transport. Regular transport routes and collection times would be fixed and reliable. Transport staff would wear adequate personal protective equipment (PPE) Education and training would be provided to all waste transport workers 	<ul style="list-style-type: none"> - BSL 3 NRL Administration - EPHI 	<p>During Operation Phase</p>	<p>25,000</p>

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> • A bulky and heavy waste would be transported by using wheeled trolleys or carts that are not used for any other purpose. • Waste, especially hazardous waste, would never be transported by hand due to the risk of accident or injury from infectious material • The vehicles would be thoroughly cleaned and disinfected daily as per a written protocol. • Collection would start from the most hygienically sensitive laboratory area 			
25. Risk associated with off-site transport of waste	<ul style="list-style-type: none"> • EPHI would follow applicable national regulations and internationally accepted standards for packaging, labelling, and transport of hazardous materials and wastes • All waste containers designated for off-site shipment would be secured and labelled with the contents and associated hazards, be properly loaded on the transport vehicles before leaving the site, and be accompanied by a shipping paper (i.e., manifest) that describes the load and its associated hazards • EPHI would use tanks and containers specially designed and manufactured to incorporate features appropriate for the wastes they are intended to carry • EPHI would adequately label all transport tanks and containers to identify the contents, hazards, and actions required in various emergency situations. • The waste would be placed in rigid, leak-proof containers before being loaded. 	<ul style="list-style-type: none"> - BSL 3 NRL Administration - EPHI - Addis Ababa municipal waste management authority 	During Operation Phase	20,000

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> Containers would be covered with lids during transportation. When transporting plastic bags of infectious waste, care should be taken to prevent tearing the bags. Vehicles used for transporting infectious waste would be disinfected prior to use for any other purpose. The vehicles shall carry adequate supplies of plastic bags, protective clothing, cleaning tools, and disinfectants to clean and disinfect in case of any spills. Records must be kept documenting all transport of medical waste 			
26. Risk associated with solid waste Treatment at EPHI	<ul style="list-style-type: none"> 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 would be provided with PPE and the use of PPE would be enforced. 	<ul style="list-style-type: none"> - BSL 3 NRL Administration - EPHI - Addis Ababa municipal waste management authority 	During Operation Phase	10, 000
27. Impact associated with final disposal of solid and liquid wastes	<ul style="list-style-type: none"> Personnel working on waste disposable would wear adequate personal protective equipment (PPE) including Training would be provided to personnel working on waste disposable Bottom ash would be managed separately from fly ash and other flue gas treatment residues to avoid contamination of the bottom ash for its potential recovery 	<ul style="list-style-type: none"> - BSL 3 NRL Administration - EPHI - Addis Ababa municipal waste 	During Operation Phase	25, 000

Potential environmental & social impacts	Proposed mitigation measures	Responsible for implementing the mitigation measures	Time Horizon	Indicative Budget for implementation (USD)
	<ul style="list-style-type: none"> Remaining ferrous and non-ferrous metals would be separated from bottom ash as far as practicably and economically viable, for their recovery bottom ash would be treated on-site by screening and crushing to the extent that is required to meet the specifications set for its use or at the receiving treatment or disposal site (e.g., to achieve a leaching level for metals and salts that is in compliance with the local environmental conditions at the place of use); Bottom ash and residuals would be managed based on their classification as hazardous or non-hazardous materials. Hazardous ash would be managed and disposed of as hazardous waste. These wastes are predominantly hazardous wastes and would be disposed of in safe landfills, and the land filling would be in proper double-walled containers. Waste disposal system would be monitored periodically 	management authority		
28. Emergency Preparedness and Response	<ul style="list-style-type: none"> Organization of emergency areas Communication systems Emergency response procedures Training and updating Checklists (role and action list and equipment checklist) Business Continuity and Contingency 	-		4,500
Total cost			1,222,000	

* The ESMP is included all unit of the BSL 3 building complex (BSL 3 lab, PTPC, Biobank. warehouse and LEMC)

8.3 Environmental and Social Risks Management & Monitoring Plan

This environmental monitoring plan, summarized in table 18, for the construction and operation works of the proposed NRL facility presents the environmental and social impacts and mitigation measures that will be monitored during project implementation. It identifies parties responsible for monitoring actions, associated costs, indicators and training or capacity building needs and reporting. Various aspects of the ESMP are detailed in sections below.

8.3.1 Institutional Arrangement for Monitoring Plan Implementation

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

Monitoring will be undertaken by FMOH PHID directorate, EPHI Environmental Officer and representative of Addis Ababa EFCC (AAEFCC) at city administration level or sub city and or Woreda level (such as Woreda 9). Monitoring by AAEFCC in this case can be considered “third party monitoring” but this is its regulatory mandate according to Pollution Control Proclamation. Another government agency that may undertake “third party monitoring” is the Occupational Health & Safety Department of Addis Ababa Labor and Social Affairs Bureau. It 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 (construction workers, residents near the institute, patients and healthcare staff).

8.3.2 Frequency for monitoring

Monitoring will be undertaken monthly over the 1-year construction period. Audits will be necessary both during construction and project operation. While construction audits will aim to verify compliance to impact mitigation requirements, post-construction audits are a regulatory requirement within 12 months and not more than 36 months after completion of construction. Since construction duration is estimated to be 3 year, this ESMP has included a budget for **3 year’s**

construction audit and a separate provision so that from year 2 to 5th (4 audits) audits done are a full environmental audit. Both construction and post-construction audits can be conducted internally by PHID/MOH or by a consultant hired by MOH.

8.3.3 Reporting System

Monthly monitoring reports should be compiled by PHID FMOH's Project Coordination Team and shared with FMOH and EPHI or another interested stakeholder. Construction- and post-construction phase auditing should finish in reports that MOH shall share with EPHI or other interested stakeholders. Note that while MOH is under obligation to disclose construction phase audits, annual post-construction audits must be submitted to Addis Ababa EPA as a guideline requirement as per EIA Proclamation, 299/2002.

Table 18: Environmental and social risks mitigation measures implementation and Monitoring Plan

Impact and Mitigation/Enhancement commitments	Desired Outcomes	Monitoring: Performance Indicators/Targets or Acceptance Criteria	Time	Responsibility	Estimated Costs (USD)	Capacity Building and Training Requirements
Negative impact						
Impact of construction and demolition waste						
Wastes will be properly segregated and separated to encourage recycling	Records of proper waste disposal indicating quantities dumped and location of dumping site. Amount of waste disposed minimized by reuse	No report of illegal waste dumping in non-designated areas Documented record of material types and estimated quantity diverted for reuse	Quarterly	AAEFCC PHID	300.00	None
Waste will be picked off the site every day and if not it will be covered to minimize nuisance odour and vermin.	Hazardous waste separated from non-hazardous waste on site and each waste stream disposed of according to Ethiopian HCWM requirements in designated sites	No of times a waste picked per day	Daily	AAEFCC PHID	3000.00	None
Impacts from physical hazards						
Ensuring safe work practices after orientation has been given	Occupational safety will be maintained	No of workers participated in the orientation	Biannually	AAEFCC	100.00	Required
Training and awareness creation on incidence handling, prevention and potential emergency	Maintains minimum work hazards	Documentation of records of training and Impromptu interviews with workers on	Biannually	PHID	200.00	Required

		occupation health safety emergency response				
Use of signage to warn staff and/ or visitors that are not involved in construction activities of dangerous places	Minimize occupation health safety risk on construction workers and the public	availability of appropriate safety signage on-site	biannually	contractors	200.00	None
Safety supervision of works would be done regularly to ensure that safety conditions are met while any deviation from safety regulations is immediately reclaimed following the best practices regarding safety at work equipment	Ensures that safety conditions are met	Presence of safety supervisor on-site	daily	Contractor	to be included in the constructors' cost	None
Develop evacuation procedures to handle emergency situations	Minimize occupation health and safety risk on construction workers	Documented Emergency Response Preparedness Plan (ERPP)	pre-construction	contractor	100.00	None
Provide appropriate personnel protective equipment (PPE) to all workers	Minimize occupation health and safety risk on construction workers	No injuries reported in any month of construction phase	daily	Contractor	to be estimated and included in the bill of quantities	None
Impact from electrical and explosive hazards						
All electrical installations and equipment would be inspected and tested regularly including earthing/ground systems	Minimize occupation health and safety risk on construction workers	Record of electrical installations and equipment inspected and tested	Construction phase	PHID	to be included in furnishing bill of quantities	None
Specialized refrigerators would be used when storing chemicals that have explosion potential	Minimize occupation health and safety risk on construction workers	No explosive chemicals in a household refrigerator placed	Construction phase	PHID	to be included in furnishing bill of quantities	None
Impact from traffic accidents						
Ensure drivers respect traffic laws and obey speed limits	No road accident by project traffic	No accident occurs in each month of construction duration	Construction phase	PHID	200.00	None
Ensure that vehicles are regularly maintained to minimize potentially serious accidents	No road accident due to poor mechanical conditions of project vehicles	No accident occurs in each month of construction duration	Construction phase	PHID	Included in the overall construction cost	None

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Employ safe traffic control measures, including temporary road signs , flag persons to warn of dangerous conditions and children crossings,	No road accident by project traffic	No accident occurs in each month of construction duration	Construction phase	PHID	100.00	Required
Impact on air quality					850.00	
Dust screens or nets in windows, doorways and ventilator will be deployed where demolition or other dusty construction activities are occurring	No excessive dust emissions noted outside construction areas	No complaints of excessive dust from construction areas	Construction phase	AAEFCC PHID Contractors	100.00	None
Ensure good housekeeping and clean construction operations where, among other necessary actions, dust would be quickly swept off cement floors and collected in covered containers	Minimize dust and exhaust emissions	No complaints of trucks reckless driving from communities along roads used by project vehicles	Construction phase	AAEFCC PHID contractors	100.00	None
To minimize indoor dust, portable extraction systems, water sprays or other practical methods are applied	Minimize dust levels	Recognition of locales of contractor's efforts to minimize dust nuisance	Construction phase	AAEFCC PHID contractors	100.00	None
Trucks would be covered during haulage of construction materials and would be diverted away from sensitive areas of the institute	No material spills on roads during haulage to sites	No accidents caused by construction material split on road	Construction phase	AAEFCC PHID contractors	250.00	None
Impact of noise and vibrations					300.00	
Construction workers will be aware of the sensitive nature of workplaces they are operating in and advised to limit verbal noise or other forms of noise. For example, metallic objects or tools can be passed on to a colleague rather than dropping or throwing them with loud bangs	No excessive noise from workers	Patients, visitors and staff do not complain about noise during construction	Construction phase	AAEFCC PHID contractors	Budget included in project cost	Training Required
All heavy duty immovable equipment will be fitted with mufflers or placed in enclosures to minimize disrupting ambient noise levels	Construction activities generate permissible levels of noise	Patients, visitors and staff do not complain about noise during construction	Construction phase	AAEFCC PHID MoLSA	100.00	None
Contractor will ensure that equipment is properly maintained and fitted with mufflers	Construction activities generate permissible levels of noise	Patients, visitors and staff do not complain about noise during construction	Construction phase	AAEFCC PHID MoLSA	Will bw included in the overall construction cost	None

Where possible, contractors would cordon off areas under construction with noise absorbing materials, for example, plywood rather than iron sheets	Keeps noise level down	Patients, visitors and staff do not complain about noise during construction	Construction phase	AAEFCC PHID MoLSA	Will be included in the overall construction cost	None
Contractor ensures noise levels emanating from machinery, vehicles and noisy construction activities are kept at a minimum	Safety, health and protection of people in the nearby buildings	Patients, visitors and staff do not complain about noise during construction	Construction phase	AAEFCC PHID MoLSA	-	None
Risks associated with the existing incinerators (before decommissioning)						
Periodical maintenance of the existing incinerators	maintained the incinerators periodically		Annually	AAEFCC, EPHI	1,000.00	
Risks associated with demolition and disposal the existing incinerators						
Avoidance of release of residue ash to the environment during demolition of the existing incinerators	No risks associated with release of residual ash	<ul style="list-style-type: none"> Decommissioning and demolition work carried out in full containment; adequate health and safety protection measures in place. Appropriate waste collection procedure in place to collect, transport and dispose the chemical wastes to the designated treatment facility Verification by EPHI and AAEFCC 	Before the BSL3 lab becomes operational/construction phase	EPHI AAEFCC The Decommissioning Company	Cost included in the decommissioning cost	none
Minimizing airborne dust associated with the demolition on the existing incinerators	No or minimized risk associated with airborne dust due to demolition activities	<ul style="list-style-type: none"> Decommissioning and demolition work carried out in full containment; adequate health and safety protection measures in place. 	Before the BSL3 lab becomes operational/construction phase	EPHI AAEFCC The Decommissioning Company	Cost included in the decommissioning cost	none

		<ul style="list-style-type: none"> • Verification by EPHI and AAEFCC 				
Avoidance of the release of asbestos containing materials and chemical waste from demolition of the existing incinerators	No risks associated with release of asbestos containing materials and chemical waste	<ul style="list-style-type: none"> • Decommissioning and demolition work carried out in full containment; • Appropriate waste collection procedure in place to collect, transport and dispose the chemical wastes to the designated treatment facility • adequate health and safety protection measures in place. • Verification by EPHI and AAEFCC 	Before the BSL3 lab becomes operational/construction phase	EPHI AAEFCC The Decommissioning Company	Cost included in the decommissioning cost	
Avoidance risks associated with wastewater from demolition activities of the existing incinerators	No risks associated with wastewater from demolition activities	<ul style="list-style-type: none"> • The floor drain in the incinerator room covered with a temporary seal during the decommissioning and demolition works. • The top of the chimney would be sealed with polyethylene sheets at least twenty-four (24) hours before the works commence • Verification by EPHI and AAEFCC 	Before the BSL3 lab becomes operational/construction phase	EPHI AAEFCC The Decommissioning Company	Cost included in the decommissioning cost	
Impact on social service caused by disruption of laboratory/ Sample collection services						

Plan pre-construction activities early to identify suitable rooms or adjoining buildings into which the sample collection can be carried out with minimal inconvenience	Sample collection relocated to a conducive room(s) with minimal interference of sample collection services	No complaints about sample collection service delivery	Pre-construction phase	AAEFCC PHID	Budget included in project cost	None
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Impacts from physical hazards						
All workers to be provided with appropriate PPE against exposure to infectious pathogens, hazardous chemicals and ionizing radiation in accordance with recognized international safety standards and guidelines.	Minimal work-related injuries or infections	All healthcare staff have necessary PPE	Daily	EPHI safety officers and respective lab head	600.00	None
Orientation for all staff would be given on safe work practices and guidelines and ensure that they adhere to it. Training would be conducted on incident handling and prevent manage. This would involve proper handling of electricity, water etc. and sensitization on various modes of escape, conduct and responsibility during such incidences.	Minimize occupation health safety risk on staff	Records of staff orientation on safety practices and guidelines	Throughout laboratory operation	EPHI safety officers and respective lab head	1000.00	Safety practices and guidelines
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	Staff preparedness to combat possible incidences	Records of incidence prevention	Throughout laboratory operation	EPHI safety officers and respective lab head	-	None
Use signage to warn staff and/ or visitors that are not involved in laboratory work of dangerous places	Public and other staff safety	Presence of appropriate and clear signage in and around laboratory facility	Throughout laboratory operation	EPHI safety officers and respective lab head	200.00	None
Impact from electrical and explosive hazards						
All electrical installations and equipment would be inspected and tested regularly, including earthing/grounding systems.	Inspected and tested electrical installations and equipment	Record of electrical installations and equipment inspected and tested	Operation phase (daily)	EPHI	-	None

All laboratory electrical equipment would be earthed/grounded	All electrical equipment earthed/grounded	Record of electrical equipment earthed/grounded	Operation phase	EPIH	-	None
Disconnect equipment attached to high-voltage or high-amperage power sources	Disconnected equipment attached to high-voltage or amperage power sources	No. of equipment attached to high-voltage or amperage power sources connected	Operation phase (daily)	EPIH	-	None
Flammable liquids will not be placed in a household refrigerator	Household refrigerator free of flammable liquids	Flammable liquids in a household refrigerator placed	Operation phase (daily)	EPIH	-	None
Impact from chemical hazard						
Only small amounts of chemicals necessary for daily use would be stored in the laboratory	Avail small amounts of chemicals necessary for daily use	Daily amounts of chemicals available in the lab	Operation phase (daily)	EPIH	-	None
Replacement of the hazardous substance with a less hazardous substitute	Less hazardous substance substitute	Less hazardous substance substitute utilized	Operation phase (daily)	EPIH	-	None
Training workers in the use of the available information (such as MSDSs), safe work practices, and appropriate use of PPE	Safe work practices and PPE	Number of personnel trained	Operation phase (biannually)	EPIH	-	Yes
Impact of escaping of infectious agents from BSL 3 labs, PTPC and Biobank centre						
Personnel working in BSL 3 lab, PTPC and biobank would be trained on sample and waste handling, transportation, and storage	Personnel working in BSL 3 lab, trained on sample and waste handling, transportation, and storage	Number of personnel working in BSL 3 lab, trained on sample and waste handling, transportation, and storage	biannually	FMOH, EPIH	1500.00	Yes
Equipment would be maintained and calibrated periodically	Equipment maintained and calibrated periodically	Certificate of Equipment maintained and calibrated periodically	Yearly	EPIH		None
BSCs HEPA filters would be tested annually and replaced as necessary.	HEPA filters maintained and calibrated periodically	Certificate of HEPA filters maintained and calibrated periodically	Yearly	EPIH		None
Effective vaccines or therapeutic measures would be available for all risk groups	Vaccinate all staffs in the risk groups	Number of vaccinated staffs in the risk groups	Yearly	EPIH		None

All material would be sterilized by autoclave or chemical disinfection	Disinfection of contaminated materials	Observing routine disinfection activities are in place	daily	EPI		None
BSL 3 lab, PTPC and Biobank would be locked always and access restricted for non-authorized personnel	Implementing access control measures in the facilities	Observing all appropriate access control measures are in place	daily	EPI		None
All agents would be contained within the laboratory and biosecurity system would be in place.	All agents contained within the laboratory in secured place	Placed agents contained within the laboratory in secured area	dialy	EPI		None
Potential Occupational Health and safety impacts associated with BSL 3 Laboratory operation						
Implement the facility containment devices and administrative controls BSL-3	the facility containment devices, and administrative controls implemented	the facility with containment devices, and administrative controls	during construction and operation	MOH, EPI	to be included in the overall project cost	None
Good Microbiological practices for the BSL 3 Laboratory	Good Microbiological practice	Good Microbiological implemented	Annually	MOH, EPI	Negligible	None
Implement special practices for BSL 3 laboratory	special practices for BSL 3 laboratory practiced	special practices for BSL 3 laboratory implemented	during the entire operation phase	MOH, EPI	-	None
Use Personal Protective Equipment during laboratory activities in BSL 3 Laboratories	Personal Protective Equipment during performing activities in used	Personal Protective Equipment available and utilized	during the entire operation phase	MOH, EPI	included above	None
Use laboratory Secondary Barriers for BSL 3 laboratory	Secondary Barriers used	Secondary Barriers in placed	during the entire operation phase	MOH, EPI	included in the construction cost	None
Potential impacts associated with operation of BSL 2 laboratories, PTPC and Biobank						
All procedures involving the manipulation of infectious materials would be conducted within BSCs or other physical containment devices and	All infectious materials processed within BSCs or other containments	Observation to ensure infectious materials processing	during the entire operation phase	EPI	cost to be included in the construction cost	No

PTPC and Biobank centre would have special engineering and design features.						
Personnel working in PTPC and Biobank centre 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	Personnel working in PTPC and biobank trained on sample and waste handling, transportation, and storage	Number of personnel working in PTPC and biobank trained on sample and waste handling, transportation, and storage	biannually	EPHI	1500	No
Impact of handling of infectious materials and specimens in the proposed BSL 3 laboratory						
Use robust and leak-proof specimen containers	Robust and leak-proof specimen containers used	Available of robust and leak-proof specimen containers used	during the entire operation phase	EPHI	cost will be included in furnishing costs	None
Personnel would be trained on specimen and waste handling, transport and storage.	Trained on specimen and waste handling, transport and storage provided	Number of trained staff on specimen and waste handling, transport and storage	during the entire operation phase	EPHI	1500	Yes
Use triple package during transportation of infectious materials	triple package during transportation of infectious materials used	Available of triple package during transportation of infectious materials used	during the entire operation phase	EPHI	-cost will be included in furnishing costs	None
Follow working procedure during handling package during transportation of infectious materials	Working procedure during handling package during transportation of infectious materials followed	Working procedure for handling package during transportation of infectious materials available	during the entire operation phase	EPHI	-	None
Impact of handling of storage of infectious materials and specimen in the proposed BSL 2 laboratories, PTPC and Biobank						
Use robust and leak-proof specimen containers	Robust and leak-proof specimen containers used	Available of robust and leak-proof specimen containers used	during the entire operation phase	EPHI	to be included in the materials procurement cost	None

Containers would be correctly labelled to facilitate identification	Proper labelling of all the containers	Observation to ensure proper labelling is in place	during the entire operation phase	EPHI		None
Specimen request or specification forms would not be wrapped around the containers but placed in separate, preferably water proof envelopes	Appropriate specimen handling	Observation to ensure specimen handling system is in place	during the entire operation phase	EPHI	cost will be included in furnishing costs	None
Secondary containers, such as boxes, would be used, fitted with racks so that the specimen containers remain upright.	Avoid accidental leakage or spillage from specimens	Number of recorded Sample spills and leakages occurred	during the entire operation phase	EPHI	cost will be included in furnishing costs	None
Impact associated with the use of equipment in the BSL 2, BSL 3 laboratory, PTPC and Biobank						
Training of workers in equipment operating and handling techniques during operation	Personnel working in PTPC and biobank trained on sample and waste handling, transportation, and storage	Number of personnel working in PTPC and biobank trained on sample and waste handling, transportation, and storage	biannually	EPHI	1500	Yes
Periodic maintenance and calibration of equipment according to manufacture recommendation.	Equipment maintained and calibrated periodically	Certificate of Equipment maintained and calibrated periodically	Yearly	EPHI	3000	None
Operation of equipment according to the manufacturer's instructions	Equipment operated according to the manufacturer's instructions	Equipment manufacturer's instructions using to operate equipment	daily	EPHI	-	None
Impact of contamination of the BSL 3, BSL 2 laboratories, PTPC and Biobank facilities						
Workers would be trained on evacuation of the contaminated area and on decontamination or disinfection	Trained staff on evacuation of the contaminated area	Number of staff trained on evacuation of the contaminated area	biannually	EPHI	1500	Yes
Rinsing, and wiping dry of the spillage area with an absorbent cloth by personnel wearing adequate protective clothing	wiping of spillage area	Number of staff trained on wiping of spillage area	daily	EPHI		Yes
Decontamination or disinfection of the protective clothing if necessary	Decontamination or disinfection of the protective clothing	Number of staff trained on decontamination or	dialy	EPHI		Yes

		disinfection of the protective clothing				
Handling and managing of spill and splash	Handling and managing of spill and splash	Number of staff trained on handling and managing of spill and splash	daily	EPHI		Yes
Potential impact during the operation of central warehouse						
Implementation of engineering and administrative control measures	Authorized personnel only	Number of staff authorized	Operation phase	MOH,EPHI	-	None
Store chemicals in a well-ventilated area, do not store chemicals in a fume hood	Properly stored chemicals	Number and type of properly stored chemicals	Operation phase	MOH,EPHI	-	None
Provide training in the use of MSDSs, safe work practices and appropriate use of PPE	Advocates appropriate handling of chemicals	Number of trained staff	Operation phase	MOH,EPHI	100.00	Yes
Maintain an inventory of all chemicals	Type and number of chemicals used and left	Number of chemicals stored	Operation phase	MOH,EPHI	-	None
Impact of fire outbreak						
All staff will have training in fire control	Declines the risk of fire hazard	Number of trained staff	Operation phase	MOH, EPHI	500.00	Yes
Fire extinguishers would be available in accessible area and ensure that all fire-fighting equipment is regularly maintained and serviced.	Laboratory has basic capacity to fend off a small or average fire outbreak	Laboratory and store should have fire extinguishers in all risk area	During equipment installation, upon completion of construction	MOH,EPHI	Negligible	None
Fire emergency telephone numbers would be displayed in communal areas.	Contact fire department in case of major fire outbreak	Fire emergency telephone numbers displaced in at least 2 communal areas	Operation phase of lab and store facility	MOH, EPHI	Negligible	None
Automatic fire alarm system for the entire laboratory will be installed	Laboratory has basic capacity to fend off a smaller or average fire outbreak	Presence of automatic fire alarm system, adequate water hose reel and reverse water tank	Operation phase of lab and store facility	MOH, EPHI	Included in the overall construction cost	None
Fire hazard signs such as 'No Smoking' signs will be provided	Laboratory will have hazard signs	Number of signs provided	Operation phase	MOH,EPHI	Negligible	None
Directions to exit in case of any fire incidence and emergency contact numbers will be provided	Laboratory has basic capacity to fend off a smaller or average fire outbreak	Presence of automatic fire alarm system, adequate water hose reel and reverse water tank	Operation phase of lab	MOH,EPHI	100.00	None

			and store facility			
Contact/emergency numbers will be displayed within the laboratory.	Laboratory has capacity to contact fire department in case of major fire outbreak	Fire emergency telephone numbers displaced in at least 2 communal areas	Throughout operation life of Laboratory and store facility	MOH,EPHI	Included in the overall cost	None
Electrical and explosive hazards in the BSL 3 NRL complex building						
All electrical installations and equipment are inspected and tested regularly	Tested and inspected equipment	Record of electrical installations and equipment inspected and tested	Operation phase	MOH,EPHI	-	None
Circuit-breakers and earth-fault-interrupters would be installed in appropriate laboratory electrical circuits	Installed circuit-breakers and earth-fault-interrupters	Record of circuit-breakers and earth-fault-interrupters installed	Operation phase	MOH,EPHI	-	None
All laboratory electrical equipment would be earthed/grounded, preferably through three-prong plugs.	All electrical equipment earthed/grounded	Record of electrical equipment earthed/grounded	Operation phase	MOH,EPHI	-	None
All laboratory electrical equipment and wiring would conform to national electrical safety standards and codes	Confirmation of equipment and wiring to safety standards and codes	Record of equipment safety standards and safety codes	Operation phase	MOH,EPHI	-	None
Ergonomic hazards in the BSL 3 NRL complex building						
Training of workers in lifting and materials handling techniques during operation	Make use of material handling techniques during operation	Number of trained workers	Operation phase	MOH,EPHI	1000.00	Yes
Planning work site layout	Minimize the need for manual transfer of heavy loads	Identified layouts	Operation phase	MOH,EPHI	-	None
Selecting tools and designing work stations	Reduce force requirements and holding times	Tools used and work stations designed	Operation phase	MOH,EPHI	-	None
Impact of air pollution due to waste incineration						
Waste segregation for wastes with polychlorinated would be done and these waste would never be incinerated	Waste with polychlorinated dibenzo-dioxins and	Waste with polychlorinated dibenzo-dioxins and	Operation phase	EPHI	25.00	None

	polychlorinated dibenzofurans PCDD/Fs segregated and not incinerated	polychlorinated dibenzofurans PCDD/Fs disposed without incinerating				
Workers will be provided with PPE and the use of PPE would be enforced	Available of adequate PPE and utilizing of PPE	Staff utilizing of PPE	Operation phase	EPHI	25.00	Yes
Improve incinerators and infrastructure for healthcare waste treatment and disposal	Implemented WB & WHO waste treatment and disposal requirements	Acceptable waste treatment and disposal system implemented	Operation phase	EPHI	25.00	None
Maintain the new incinerators to be installed periodically	Periodically maintained incinerators	Frequency of periodically maintained incinerators	Operation phase	EPHI	2000	None
Purchase new environmental friendly incinerator and agreement for training, maintenance and supplying spare parts would be signed see annex 7 for detail specification	A new environment friendly Pyrolytic incinerator purchased & installed	Functional environment friendly Pyrolytic incinerator	Operation phase	EPHI	This cost will be included in the project implementation cost	None
	Signed agreement between supplier and EPHI for training, maintenance and supplying spare parts	Documented signed agreement between supplier and EPHI	Operation phase	EPHI		
Misuse and/or theft of infectious agents and laboratory equipment/supplies in the BSL 3 NRL complex building						
Strict Biosecurity measures would be implemented	Limits access to facilities, research materials and information	Access limited	Operation phase (daily)	EPHI	-	None
Continue the use of digital inventory system for both the microorganisms and equipment	Inventory of equipment and organisms	Inventories applied in the lab	Operation phase (daily)	EPHI	-	None
Develop measures to protect against the insider threat (employees, staff, or contractors), or outsider threat (outsiders who intend to gain access to do harm) and any natural or manmade events	Defines security and bio security in the context of the lab	Legal procedures developed	Operation phase (daily)	EPHI	-	None
Establish system for physical security, personnel security, material control & accountability, and information security	Develop security practices and communication	System established for physical, personnel and material control	Operation phase (daily)	EPHI	1500	,None

All staff will have training in laboratory security and biosecurity	Understanding and practicing security issues	Number of staff trained	Operation phase	EPHI	1000.00	Yes
All BSL 3 labs, BSL2 labs, Biobank and PTPC would always be locked and non-authorized personnel forbidden to enter the facilities without permission.	Restricts access to facilities	Number of controlled gates and doors	Operation phase	EPHI	-	None
Gender based violence impacts						
Conduct continued sensitization and awareness raising to EPHI staff in general and BSL-3 NRL staff in particular on prevention of GBV	Awareness creation	Number of staff trained	Continued sensitization	EPHI	100.00	Yes
Strengthen the Gender and women office of EPHI to address GBV cases when it occurs	Strengthened office of GBV	Office strengthened	Whenever necessary	EPHI	100.00	Yes
Impact associated with collection/handling and storage of waste at BSL 3 Lab complex building						
Initial packaging and storage would take place where HCW is generated	Packaging and storage area for waste available	storage area with packaging for waste available	daily	EPHI	-	
Non-risk HCW would always be stored in a separate location from the infectious/ hazardous HCW in order to avoid cross-contamination	Available space for non-risk HCW storage	Non-risk HCW stored in a separate location	daily	EPHI	-	
Strengthen the internal waste management system (collection, storage and disposal) of the EPHI and equip it with additional facilities to allow for segregated collection at source	Well established waste management system	Well established waste management system implemented	Quarterly	EPHI	-	
All sharps used in the BSL-3 would be autoclaved prior to incineration.	System for sharps used in the BSL-3 autoclaved available and utilized	Shapes used in the BSL-3 autoclaved	dialy	EPHI	-	
Sharps would be placed in rigid, puncture-resistant containers made of glass, metal, rigid plastic, or cardboard	Rigid, puncture-resistant containers made of glass, metal, rigid plastic, or cardboard for Sharps available and utilized	Sharps placed in rigid, puncture-resistant containers made of glass, metal, rigid plastic, or cardboard	daily	EPHI	-	
Liquid infectious wastes would be placed in capped or tightly stopped bottles or flasks; large quantities may be placed in containment tanks	Capped or tightly stopped bottles or flasks; large quantities used for Liquid infectious wastes available and utilized	Capped or tightly stopped bottles or flasks; large quantities used for Liquid infectious wastes	daily	EPHI	-	

Solid or semisolid wastes would be placed in tear-resistant plastic bags judged by their thickness or durability	tear-resistant plastic bags for solid or semisolid wastes available	Solid or semisolid wastes placed in tear-resistant plastic bags judged by their thickness or durability	daily	EPHI	-	
Solid waste generated in the BSL-3 laboratory would leave the laboratories only after decontamination using the laboratory's autoclave	Autoclave available for Solid waste generated in the BSL-3 laboratory	Solid waste generated in the BSL-3 laboratory autoclaved	daily	EPHI	-	
Liquid Waste discharged from laboratory would be treated chemically prior to being released to the waste tank	Liquid Waste discharged treatment system available	Liquid Waste discharged from laboratory treated	Quarterly	EPHI	-	
Liquid waste treatment plant would be constructed at EPHI to improve the capacity of the tank	Functional robust treatment facility.	constructed septic tank at EPHI	Once	MOH/EPHI	-	
Laboratory staff and all other staff involved in waste handling would be trained on the waste handling treatment, and disposal techniques	Improved waste collection/handling and storage capacity	Documentation of records of training	biannually	EPHI	1500	
Fumigation of the laboratory by disinfectant gases would be conducted according to WHO laboratory manual	Fumigated Laboratories free of infection	Records of fumigations performed	daily	EPHI	-	
Regular audits of waste segregation and collection practices	Improved waste segregation and collection practices	Records of audits performed	weekly	EPHI	-	
Tracking of waste generation trends by type and amount of waste generated, preferably by facility departments	Amount of waste generated and its destination	Manifests or other records kept	weekly	EPHI	-	
Risks associated with waste transportation within EPHI campus						
All waste bags would in-place and intact at the end of transportation	Designated pathways for waste transportation	Available routes in place	daily	EPHI	1000	None
Carts, trolley, or containers, used for the transportation of infectious waste would not be used for the transportation of any other material	Have separated trolley and carts for sharps, infectious and infectious waste transportation	Availability of color-coded Carts, trolley or containers for each type of wastes	daily	EPHI	-	None
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	Maintained secondary containment	Presence of appropriate secondary barrier	daily	EPHI	-	Yes

The collected waste will not be left even temporarily anywhere other than at the designated storage room	Wastes stored only at designated storage area	Presence of wastes other than designated place	daily	EPHI	-	None
Containers would be covered with lids during storage and transport.	Waste storage and transportation	Availability of waste storage and transportation bin with lid	dialy	EPHI	-	None
Transport staff would wear adequate personal protective equipment (PPE)	Regular use of PPE by waste transport staff	Use of PPE by waste transport staff	dialy	EPHI	-	None
Education and training would be provided to all waste transport workers	Trained waste handlers	Number of trained waste handlers	biannually	EPHI	1500	None
A bulky and heavy waste would be transported by using wheeled trolleys or carts that are not used for any other purpose	A bulky and heavy waste would be transported by using wheeled trolleys or carts that are not used for any other purpose	Minimized risk associated with transport of waste	daily	EPHI	-	None
Waste, especially hazardous waste, would never be transported by hand due to the risk of accident or injury from infectious material	Waste, especially hazardous waste, would never be transported by hand due to the risk of accident or injury from infectious material	Minimized accident or injury from infectious materials	daily	EPHI	-	None
The vehicles would be thoroughly cleaned and disinfected daily as per a written protocol	The vehicles would be thoroughly cleaned and disinfected daily as per a written protocol	Clean and disinfected vehicles	dialy	EPHI	250.00	None
Risk associated with off-site transport of waste						
EPHI would follow applicable national regulations and internationally accepted standards for packaging, labelling, and transport of hazardous materials and wastes	Standardized transport of hazardous materials and wastes	Regulations and standards	Throughout the operation	AAEFCC, EPHI		None
EPHI would use tanks and containers specially designed and manufactured	Tanks will be appropriate for the wastes they are intended to carry	acceptable tanks in use	Throughout the operation	AAEFCC, EPHI	To be included in furnishing cost	None
EPHI would adequately label all transport tanks and containers	Identifies the contents, hazards, and actions	adequacy of the labelling practice	Operation phase	AAEFCC, EPHI	-	None

	required in various emergency situations.					
Containers would be covered with lids during transportation	Containers covered with lid	Available containers with lid	Operation phase	AAEFCC, EPHI	-	None
Vehicles used for transporting infectious waste would be disinfected prior to use for any other purpose	Disinfected vehicles	Number of vehicles disinfected	Operation phase	AAEFCC, EPHI	-	None
Vehicles shall carry adequate supplies of plastic bags, protective clothing, cleaning tools, and disinfectants	Minimizes hazard through cleaning and disinfection in case of any spills	Amount of cleaning supplies	Operation phase	AAEFCC, EPHI	-	None
Records must be kept documenting all transport of medical waste	Recorded transported wastes	Number of records	Operation phase	EPHI	-	None
Risk associated with solid waste treatment at EPHI						
Waste segregation for wastes with polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs would be done and these waste would never be incinerated	Segregated waste with polychlorinated dibenzo-furans PCDD/Fs	Waste segregation system in place	Operation phase	MOH,EPH	-	None
Materials free of polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs would be purchased, for minimizing the environmental and health impacts.	Purchased materials free of polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs	Purchased materials free of polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans PCDD/Fs	Operation phase	MOH,EPHI	-	None
Impact associated with final disposal of solid and liquid wastes						
Personnel working on waste disposable would wear adequate personal protective equipment (PPE)	Reduced exposure to wastes	Types and number of PPE	Operation phase	AAEFCC, EPHI	-	None
Training would be provided to personnel working on waste disposable	Defines the concept of waste disposal and safety	Number of staff trained	Operation phase	AAEFCC, EPHI	1000.00	Yes
Bottom ash would be managed separately from fly ash and other flue gas treatment	Avoid contamination of the bottom ash for its potential recovery	Amount of bottom ash managed	Operation phase	AAEFCC, EPHI	-	None
Bottom ash would be treated on-site by screening and crushing to the extent that is	Helps achieve a leaching level for metals and salts	Amount of bottom ash treated	Operation phase	AAEFCC, EPHI	-	None

required to meet the specifications set for its use or at the receiving treatment or disposal site	that is in compliance with the local environmental conditions at the place of use					
Bottom ash and residuals would be managed based on their classification as hazardous or non-hazardous materials	Classified bottom ashes	Types of bottom ashes	Quarterly	AAEFCC, EPHI	-	None
Predominantly hazardous wastes would be disposed of in safe landfills, and the land filling would be in proper double-walled containers	Safe landfill disposal	Types of hazardous wastes	Quarterly	AAEFCC, EPHI	1000	None
Waste disposal system would be monitored periodically	identified technical problems and technology updates	Periodical monitoring	Quarterly	AAEFCC, EPHI	2000.00	None
Ground water monitoring within EPHI campus	identified any pollution of ground water	Record of quality of ground water periodical monitored	Quarterly	AAEFCC, EPHI	2500.00	None
Incinerators of wastewater treatment system management	identified any pollution from fly ash and flue gas	Record of emission from incinerator periodical monitored	Quarterly	AAEFCC, EPHI	1000.00	None
The new incinerator would be monitoring for proper functionality periodically	identified any defect or malfunction of incinerator	Record of preventive maintenance of incinerator periodical monitored	Quarterly	AAEFCC, EPHI	500.00	None
Total cost			38,275.00 USD³			

³ Note that some cost are not included to be more realistic. This would be included in the operation phase.

8.4 Capacity Development and Training

The development and operation of the proposed BSL 3 National reference laboratory needs to have a strong Environment, Health and Safety (EHS) monitoring and inspection capacity that will ensure installation and observance of all safety features and protocols in the proposed BSL 3 NRL project. In addition, capacity is needed to ensure monitoring of the ESMP implementation both during construction and operation phases of the proposed project. At present it appears that both the EPHI and FMOH PHID directorate lacks a dedicated EHS unit or dedicated personnel responsible for planning and implementing EHS activities. Thus there is a need for capacity development by providing technical support and training in the areas of BSL-3 laboratory safety, workers and community safety, as well as in environmental monitoring for both the EPHI and FMOH PHID directorate.

The training in the areas of BSL-3 laboratory safety, workers and community safety, as well as in environmental monitoring for implementation monitoring will be provided to relevant staff of FMOH PHID, EPHI, AAEFCC and AABoLSA to enhance their skills in environmental monitoring during the operational phases of the NRL BSL-3 laboratory. Furthermore, training needs identified for waste management are provided on the Infection Control and Waste Management Plan (ICWMP) for BSL-3 Lab document. The budget for technical support and capacity building training will be **79, 500.00 USD**. See table 19 for trainings plan for BSL 3 staff and support staff.

Table 19: Trainings plan for BSL 3 Staff and Support Staff

Capacity Needs	Target Participant	Number of participants	Estimated Cost (Usd)
Training on Infection control and waste management	<ul style="list-style-type: none"> Professionals working in BSL 3 NRL Complex (BSL 3 Laboratory, PTPC, biobank Centre, Central Warehouse, and LEMC) 	70	6,000.00
	<ul style="list-style-type: none"> Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators and other staff of the BSL 3 laboratory 	24	
Training on OSHA and environmental safety	<ul style="list-style-type: none"> Wastewater treatment Plant Operator, Incinerator Operator, Waste handler, Laboratory Director, Laboratory scientist, Laboratory quality Manager \ Biosafety and biosecurity Officer and other pertinent staff 	70	6,000.0
Training on biosafety and biosecurity	<ul style="list-style-type: none"> Professionals working in in BSL 3 NRL Complex (BSL 3 Laboratory, PTPC, biobank Centre, Central Warehouse, and LEMC) 	70	6,000.00
	<ul style="list-style-type: none"> Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility 	24	

	operators and other staff of the BSL 3 laboratory		
Quality management system	<ul style="list-style-type: none"> Professionals working in in BSL 3 NRL Complex (BSL 3 Laboratory, PTPC, biobank Centre, Central Warehouse, LEMC and other staff of the BSL 3 laboratory) 	70	4,500.00
Specimens management	<ul style="list-style-type: none"> Professionals working in in BSL 3 NRL Complex (BSL 3 Laboratory, PTPC, biobank Centre, Central Warehouse) Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators and other staff of the BSL 3 laboratory 	70 24	6,000.00
Training on emergency preparedness and response	<ul style="list-style-type: none"> Professionals working in in BSL 3 NRL Complex (BSL 3 Laboratory, PTPC, biobank Centre, Central Warehouse, and LEMC) Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators and other staff of the BSL 3 laboratory 	70 24	6,000.00
Specific Laboratory technique (microbiology, molecular methods and other related training)	<ul style="list-style-type: none"> Professionals working in in BSL 3 NRL Complex (BSL 3 Laboratory, PTPC, and biobank Centre) 	46	30,000.00
Training for BSL 3 lab bioengineers and technicians for maintenance team	<ul style="list-style-type: none"> Bioengineers 	20	5,000.00
Training on handling pathogenic and potentially lethal agents	<ul style="list-style-type: none"> Professional working in PTPC and biobank Centre 	16	5,000.00
Training on use of MSDSs, safe work practices, and appropriate PPE	<ul style="list-style-type: none"> Professional working in in BSL 3 NRL Complex (BSL 3 Laboratory, PTPC, biobank Centre, Central Warehouse, and LEMC) Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators and other staff of the BSL 3 laboratory 	70 24	5,000.00
Total			79,500.00

8.5 Chance finds and GRM procedure

8.5.1 Grievance Redress Mechanism

It is anticipated that the construction and operational phase activities of the proposed BSL 3 NRL 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 objectives of the grievance process are:

- Ensure that appropriate and mutually acceptable corrective actions are identified and implemented to address complaints;
- Verify that complaints are satisfied with outcomes of corrective actions;
- Avoid the need to resort to judicial proceedings.

The grievance mechanism at the EPHI will be fed from three main sources:

- Community residents, patients or health workers.
- Supervising engineer works supervisor or contractor.
- Monitoring team who will forward issues/concerns identified in the field.

8.5.1.1 GRM during construction phase

During the construction phase of the proposed BSL 3 NRL project, the proponent (FMOH PHID /EPHI) and the contractor will jointly set up a project specific GRM with a team comprising of construction supervisor, and delegated officers from the PHID and PCT who will receive and log, and address any disputes, conflicts or concerns arising from stakeholders that may be aggrieved by the project.

The grievance redress team will liaise with the contractor and proponent in developing the redress actions and communicate with the aggrieved stakeholders any resolutions made. Thereafter, the aggrieved stakeholders will be involved in monitoring and evaluation of the redress actions to assess their effectiveness.

8.5.1.2 GRM during operation phase

During the operation phase of the laboratory, the grievance process steps outlined below and in Figure 17 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 3 laboratory operation can use it.

Steps of the grievance process are described below. A flow chart outlining the main actions and decision points is shown in Figure 17

Step 1: Receipt of complaint

A verbal or written complaint from a complainant will be received by the head of the complaint hearing office and recorded in a complaints log. The log will indicate grievances, date lodged, action taken to address complaint or reasons the grievance was not acted on; information provided to complainant and date the grievance was closed. Grievances should be lodged at work hours, directly to the complaint hearing office.

The process for lodging a complaint is outlined below:

- Complaint hearing officer receives complaint(s) from complainant and records it in log.
- Complaint hearing officer reads the recorded complaint to confirm correct detail of complaint has been documented.
- Complainant signs the log to confirm grievance was accurately recorded.

The head of the complaint hearing office will be the focal person for the GRM process and he/she will be the first point of contact to trigger the mechanism.

Step 2: Determination of corrective action

A grievance can be solved at this stage, the complaint hearing office will determine a corrective action in consultation with the aggrieved person. Remedial action(s) and timeframe within which they must be accomplished has been described and the party responsible for implementing them will be recorded in the complaint log. ***Grievances will be resolved and status reported back to complainants within a week.*** If more time is required this will be communicated clearly and in advance to the aggrieved person. For cases that are not resolved within the stipulated time, detailed investigations will be undertaken and results discussed not more than 1 month from lodging a grievance.

Step 3: Meeting with the complainant

The proposed corrective action and the timeframe in which it is to be implemented will be discussed with the complainant within a week of receipt of the grievance. Maximum duration for the Consent to proceed with the corrective action will be sought from the complainant.

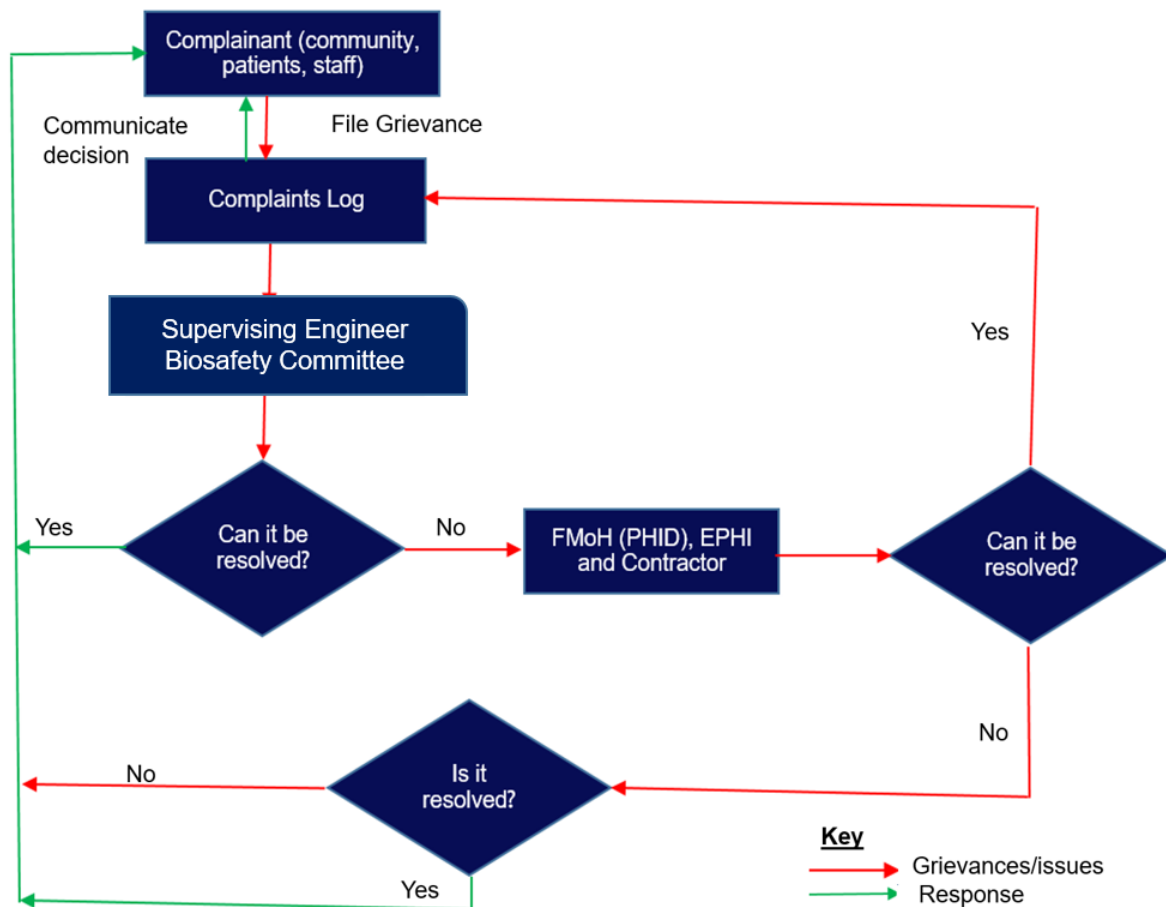


Figure 18: Grievance management mechanism

Step 4: Implementation of corrective action

Agreed corrective action will be undertaken by the project or its contractor within the agreed timeframe. The date of the completed action will be recorded in the log against the complainant’s grievance.

Step 5: Verification of corrective action

To verify satisfaction, the aggrieved person will be asked to return if not satisfied with the corrective action.

Step 6: Action by MOH and project contractors

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

8.5.2 Requirements for Chance find during construction

Requirements for chance finds are outlined in Article 41 of the Research and Conservation of Cultural Heritage Act (Proclamation No 209/2000): 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 shall report to the Authority and protect and keep same intact until the Authority takes delivery thereof". The Authority shall 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.

The procedures to avoid damage to cultural property would include carrying consultations with the appropriate authorities and local inhabitants to identify known or possible sites during project planning. Construction procedure for dealing with "chance finds includes cessation of work until the significance of a "find" has been determined by the appropriate authorities and local inhabitants, and until fitting treatment of the site has been determined and carried out.

9 Conclusion and Recommendation

This Environmental and Social Impact Assessment (ESIA) has been prepared to guide project implementers and other stakeholders to address and mitigate the identified environmental, health and social impacts of the Project. The proposed ACRIFP project has potential to significantly improve quality of healthcare services through providing quality laboratory services and efficiency of service provision in the Ethiopia as well as Sub-region with socio-environmental benefits such as reduced morbidity and increased productivity of labor. Hence higher household incomes; opportunity to have access to improved diagnostic laboratory services. Besides, project development and operation will provide considerable economic opportunity for material/ equipment suppliers, construction contractors and medical professionals.

Major significant negative impacts will mainly arise from demolition and excavation activities (dust emissions, noise and vibrations) and disruption of access to laboratory/sample collection services during construction since the sample collection site to be modified is located. These impacts would be minimized if the contractor is implementing all mitigation during construction activities.

Regarding medical waste, the institute has an established waste handling system and there are two functional incinerators for handling medical and laboratory waste. However, in order to improve the existing situation, the recommended mitigation measures should be implemented according to the guidelines. In the course of implementation, however, negative environmental and social impacts have been identified during assessment, there should storing monitoring and evaluation system for the planned mitigation to address all negative environmental and social impacts.

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Annexes

A. Annex 1: Minutes of Community Consultation (First Round)

Minutes of Community and Stakeholder Consultation **(Translated from Amharic Language)**

Stakeholder and public consultation was conducted on January 22, 2019 at the Ethiopian Public Health Institute meeting hall with participants drawn from elders, representatives of religious institution and with members of the different sector offices from woreda 09 in Gulele Sub City; and also participants from the EPHI. The objective of the public consultation was to solicit the views and opinions of the participants towards the construction of the BSL 3 laboratory.

A total of 22 people attended the public consultation and 15 of the participants were from the woreda sector offices and representatives of elders and religious institutions; and the other 7 participants were from the Ethiopian Public Health Institute.

Background to the Project: During the consultation, the participants were briefed on the objectives and purpose of the BSL 3 laboratory construction by the National Laboratory Capacity Building Directorate Director Ato Addisu Kebede and by the Project coordinator Dr. Eyob Abera.

Benefits of the proposed project for the country

The construction of BSL 3 laboratory if developed will be the biggest laboratory in the country and envisaged to provide its service to other African countries as well. It will contribute in providing high level laboratory service and is expected to resolve and reduce issues that are related to both health and social problems. When it becomes operational in future the number of tests that used to be sent outside of the country is expected to reduce drastically.

Positive impacts due to the project

Participants of the consultation meeting have raised the following positive impacts and the measures that contribute to strengthen it.

1. The construction of the laboratory is expected to contribute in providing high level medical service and the community is highly positive about its construction and is waiting anxiously.
2. The project is expected to create employment opportunity to the local unemployed youth during its construction phase.
3. In its operation phase the laboratory will employ highly skilled and trained professionals and is expected to adopt new and improved technologies.
4. It will allow conducting laboratory tests of highly infectious and chronic disease and is expected to reduce the sending of sample for test outside of the country.
5. The construction of the laboratory will enable diagnosing some chronic and critical health problems and diseases that affect mothers and children in particular.

Measures to strengthen the positive impacts

1. To speed up all the studies that will allow the starting of the construction of the laboratory on planned time without wasting time.
2. The woreda administration and the sector offices under the woreda jurisdiction are willing to provide all required assistance and support from them.

Potential Negative Impacts on the community and Environment

1. Labour issues: During the construction phase of the laboratory, either the main contractor or his sub contractors should follow FDRE laws and regulation in the employment of construction workers, ensuring labour standards, on time settling of payments and the like. To follow such measures allows the contractor and his sub contractors to have peaceful working environment.
2. Occupational health and safety: The contractor and his sub contractors are expected to follow standard occupational health and safety standards during the construction phase of the project.
3. Disposing waste materials: During construction and operation phase it is advised to dispose both solid and liquid waste with affecting the community and the environment in recognized standards.
4. Blocking roads: During construction work, the contractor should avoid storing construction materials, parking of construction machineries and trucks on vehicular and pedestrian walkways.
5. Ensure that installation of glasses on windows and other parts of the building do not have negative impact on the community and environment. The glasses to be installed should be as per the standard of the country.
6. Financial management: All financial issues that are related with the project should follow standard financial management procedures and guidelines and be free from corruption and embezzlement.

Mitigation measures to minimize the negative impacts

1. Establish mechanisms that will allow woreda sector office professionals to carry out follow up and monitoring of the project activities.
2. Ensure that the contractor carries out the construction works as per the rules, regulations and standards of the Environmental Protection Agency.
3. Ensure that the contractor follows occupational, health and safety standards; and labour regulations in employment of his workforce.
4. Monitor the contractor adopts Environmental protection guidelines and procedures
5. Monitor that the financial management system is established as per the law.

Impacts on historical and religious and cultural heritages

According to FDRE proclamation on historical, cultural and religious heritages there are not any recognized and registered historical, cultural and religious heritages site in the project area.

List of participants of the stakeholders and Public consultation

S.N	Name	Sex	Organization	Responsibility
1	Bekalu Tamir	M	Office for regulating law & order	Supervising Officer
2	Fire Hailu	F	Office for regulating law & order	Supervising Officer
3	Nuralah Imam	F	Labour and Social Affairs office	Expert
4	Nazirawi Tsega	F	Labour and Social Affairs office	Expert
5	Meri Bela	F	Environmental Protection	Expert
6	Aster Keneni	F	Women's Affair Office	Expert
7	Senait Sedom	F	Women's Affair Office	Expert
8	Sewagegne Desalegne	M	Health Office	Expert
9	Alemu Minlargilih	M	Health Office	Head
10	Mahider Gebeyehu	F	Culture & Tourism Office	Certification Expert
11	Alem Teklu	F	Culture & Tourism Office	Supervisor
12	Daniel T/Mariam	M	Elders representative	Elder
13	Bekure Fisseha	M	Rufael Church representative	Supervisor
14	Bekalu Hawaz	M	Rufael Church representative	Supervisor
15	Kirubel Tesfaye	M	EPHI	Researcher
16	Melaku Gizaw	M	EPHI	Researcher
17	Mesay Getachew	M	EPHI	Researcher
18	Daniel Abera	M	EPHI	Researcher
19	Jemanesh Kumera	F	Woreda 09 Administration	Chie Executive
20	Yeabkal Daniel	M	EPHI	Researcher
21	Eyob Abera	M	EPHI	Researcher
22	Ahmed Mohammed	M	EPHI	Researcher



Photo plate 1: Showing the Community and stakeholder Consultation Meeting

BSL 3 ላቦራቶሪ ግንባታ ዙርያ ከወረዳ 9 ማህበረሰብ ጋር የሚደረግ ውይይት አጀንዳ

1. ስለግንባታው ፕሮጀክቱ ገለጻ ማድረግ
2. የግንባታውን ፕሮጀክት ለአካባቢ እና ማህበረሰቡ ያለው ጠቀሜታ ገለጻ ማድረግ
3. የፕሮጀክቱ ግንባታው በአካባቢ ላይ የሚያስከትለው ተፅዕኖና የመፍትሄ አቅጣጫ
4. የፕሮጀክቱ ግንባታው በአካባቢ ላይ የሚያስከትለው ተፅዕኖና የመፍትሄ አቅጣጫ
5. ግንባታው በሚካሄድበት ዙሪያ ልዩ ትኩረት የሚሹ ቦታዎች (ታሪካዊ፣ ሀይማኖታዊ) ካሉ የመፍትሄ አቅጣጫ

የሰብሰባ ቦታ: ኢ. ሀ. ጤ. ኢ የሰብሰባ አዳራሽ

ቀን: ጥር 14/2011 ዓ.ም

ስለግንባታው ፕሮጀክቱ የተደረገ ውይይት

1. ስለግንባታው ፕሮጀክቱ ገለጻ ማድረግ

የኗሮ ጌጃቸውን ግንባታ = በሚመስሉት = የኗሮ ጌጃቸው = አስተገባሪ
 ባለሙያ = ኢትዮጵያ = አባቶች = አዲስ = ነበረ = የባህሪ = ካብሬት = ለሌሎች =
 የአንዳው = ግንባታው = አምሳይ = ከሌሎች = ገለጻ = አይረገግም = ይህ = ካብሬት
 ለተጨማሪ = አምሳይ = በአዲስ = ገለጻ = ካብሬት = ይህ = አንዳው
 ለመጨረሻ = ካብሬት = በአገሪቱ = ለሌሎች = አንዳው = በሙሉ = አገልግሎት
 ይሰጣል።

2. የግንባታውን ፕሮጀክት ለአካባቢ እና ማህበረሰቡ ያለው ጠቀሜታ ገለጻ ማድረግ

የካብሬት = ግንባታ = በአዲስ = ገለጻ = የጠፋ = ካብሬት =
 አንዳው = አዲስ = አገሪቱ = ለሌሎች = አገልግሎት = የሚሰጥ =
 በሙሉ = ያለው = ጠቀሜታ = አዲስ = ለሌሎች = አገልግሎት =
 ግንባታው = አዲስ = በአገሪቱ = ይህ = የካብሬት = አገልግሎት
 ለሌሎች = የአገሪቱ = የጠፋ = አገልግሎት = አንዳው =
 ነበረ = ግንባታ = የሌሎች = ግንባታ = ጠቀሜታ =
 አገልግሎት = አገልግሎት = ይህ = በተመሳሳይ = አዲስ =
 ውጭ = የሚሰጥ = የተለየ = ለሌሎች = ለሌሎች =
 ለሌሎች = ካብሬት = አገልግሎት = ይህ =

①



3. የፕሮጀክቱ ግንባታው በአካባቢ ላይ የሚያስከትለው ተፅዕኖና የመፍትሄ አቅጣጫ?

3.1 የፕሮጀክቱ ግንባታው በአካባቢ ላይ የሚያስከትለው ^{አዎንታዎ} ተፅዕኖና

የክብካቤ ግንባታ = ተሳታፊዎች = የሚከተሉት = ግንባታ = ግንባታ = ግንባታ = ~~የፕሮጀክቱ~~ አዎንታዎ ተፅዕኖ =
 አንድ ዓይነት መጠን = ግንባታ =

1. የክብካቤ ግንባታ = መንግሥት = አገልግሎት = አገልግሎት = ክፍተት = የጤና = አገልግሎት = አገልግሎት =
 የሚያገኙት = በመሆኑ = አገልግሎት = በጉዞ = አንድ ዓይነት መጠን = ግንባታ =
2. አገልግሎት = አገልግሎት = ገቢ = ገቢ = ወጪዎች = በግንባታ = ወጪዎች = የገቢ = ወጪዎች = ወጪዎች =
3. ግንባታ = ከጠናቀቅ = በሌላ = ሌላ = ሌላ = የሰላም = ሌላ = ወጪዎች = ወጪዎች =
4. አገልግሎት = ወጪዎች = ክፍተት = የጤና = ገንዘብ = የገንዘብ = በገንዘብ = የክብካቤ ግንባታ = ግንባታ =
 በአገልግሎት = ግንባታ = አንድ ዓይነት መጠን = ወጪዎች = የሚከተሉት = የገንዘብ = የገንዘብ = የገንዘብ =
5. የክብካቤ ግንባታ = መንግሥት = በተለይ = አገልግሎት = አገልግሎት = አገልግሎት = የሚከተሉት =
 በገንዘብ = አገልግሎት = አገልግሎት = ወጪዎች (የሰላም) =

3.2 የመፍትሄ አቅጣጫው

1. ግንባታ = በተቀረጸው = የገንዘብ = ገንዘብ = አንድ ዓይነት መጠን = ~~የገንዘብ~~
 አገልግሎት = ገንዘብ = በአገልግሎት = ተጠናቆ = ወጪዎች = አንድ ዓይነት መጠን =
 ወጪዎች =

2. የወጪዎች = መለኪያ = የክፍያ = መጠን = ወጪዎች = የፕሮጀክቱ
 ግንባታ = አገልግሎት = የሚከተሉት = ወጪዎች = አገልግሎት =
 ተጠናቆ =



5. ግንባታው በሚካሄድበት ዙሪያ ልዩ ትኩረት የሚሹ ቦታዎች (ሪካዊ፣ ሀይማኖታዊ) ካሉ የመፍትሄ አቅጣጫ?

በኢትዮጵያ = የተሰጠው = አርባ = ምዝገባ = ደንብ = ሕግ = መሠረት
 በአገገባቢ = በተሰጠው = ሃይማኖታዊ = አርባ = ተመዝግቦ፡
 የሚገኝ = ጠቅላይ = አካላዊ ገንጠል = ~~የሕግ~~ የሕግ ማህበራዊ = ግንባታ፡
 የሚያስተዳድሩት = የሚያደርጉት = ገንዘብ = አደናቃ፡፡



(4)

**Community and Stakeholders Consultations Attendance Sheet for Environmental and Social Assessment for
Construction of BSL 3 Reference Laboratory at Ethiopian Public Health Institute (EPHI)
Federal Democratic Republic of Ethiopia Ministry of Health**

Regions Addis Ababa Sub City Gullele Woreda 9
Date of Consultation January 22, 2018

S.N/ ተ.ቁ	Name of Participants/ የተጠቃሚው ስም	Sex ፆታ	Organization/የግንባራ ቤቅ	Position/ የክ. ደርጅ	Phone No./ ስልክ ቁጥር	Signature/ ፊርማ
1	አቶ ልግሳ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
2	ፊት ህይወት	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
3	የህዝብ ግንኙነት	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
4	የህዝብ ግንኙነት	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
5	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
6	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
7	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
8	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
9	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
10	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
11	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
12	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
13	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
14	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
15	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
16	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
17	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
18	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
19	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
20	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
21	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
22	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	
23	የቢሮ ሰነድ	♂	የቢሮ/የግንባራ	አዲስ አበባ	0911231223	



**Minutes 2 for of Community and Stakeholder Consultation for discloser of BSL 3 NRL
ESIA**

Minutes of Community and Stakeholder Consultation

(Translated from Amharic Language)

Stakeholder and public consultation was conducted on February 28, 2019 at the Ethiopian Public Health Institute meeting hall with participants drawn from elders, representatives of religious institution and with members of the different sector offices from woreda 09 in Gulele Sub City; and also participants from the EPHI. A total of 16 people attended the public consultation and 12 of the participants were from the woreda sector offices and representatives of elders and religious institutions; and the other 4 participants were from the Ethiopian Public Health Institute. The objective of the public consultation was to solicit the views and opinions of the participants towards the prepared ESIA report for construction of the BSL 3 laboratory at EPHI.

Project Background: During the consultation, the participants were briefed on the objectives and purpose of the BSL 3 laboratory construction by the National Laboratory Capacity Building Directorate Director Ato Addisu Kebede and by the Project coordinator Dr. Eyob Abera.

The presentation was focused on potential impacts of the project and proposed mitigation measures the impacts of during construction and operation phases and the presentation was as follow:

Positive Impacts of the project

The operation of BSL 3 laboratory will contribute a lot for public health emergency management in providing high level laboratory service resulting, improving community health at large

The proposed project has a positive impact on

- Employment, Gender and Labor Influx
- Improved medical surveillanc services
- Employment opportunities:

Negative Impacts during Construction Phase

- Impacts on Ecological Resources and Biodiversity
- Impact on Geology/Soils
- impact due to improper construction and demolition waste management
- Impacts on the health and safety of construction workers' and community health(physical, electrical, and Explosive Hazards
- Traffic accident impacts
- Impact on Air Quality
- Impact of Noise and Vibration
- Impact on social service through disruption of laboratory/ sample collection services
- Analysis of Abnormal Events and Accident Scenarios

Negative Impacts during Operation Phase

- Negative Impacts during Operation Phase were
- Impacts on Ecological Resources and Biodiversity
- Impacts on Geology/Soils
- Occupational Health and Safety and Community Health Concerns
- Impact of escaping of Infectious Agents from BSL-3 Containment
- Impact of escaping of Infectious Agents from BSL 2 labs, PTPC and biobank centres
- Potential Occupational Health and safety impacts associated with BSL 3 Laboratory operation
- Mitigation Strategies for Potential Occupational Health and safety impacts associated with BSL 3 Laboratory operation
- Potential impacts associated with operation of BSL 2 laboratories, PTPC and biobank
- Impact of handling of infectious materials and specimens in the proposed BSL 3 laboratory
- Risk associated with handling and storage of infectious materials and specimens in the proposed BSL 2 laboratories, PTPC and Biobank
- Impact of improper use of equipment in the BSL 3 laboratory
- Impact of improper use of equipment in the BSL 2 labs, PTPC and Biobank
- Impact of contamination of the BSL 3 laboratory, BSL 2 laboratories, PTPC and Biobank Facilities

- Potential impact during the operation of Central Warehouse
- Impact of fire outbreak
- Chemical hazard in the BSL 3 NRL complex building
- Electrical and explosive hazards in the BSL 3 NRL complex building
- Impact of air pollution due to waste incineration
- Impact due to Improper Waste Management
- Risk associated with collection/handling and storage of waste at BSL 3 NRL complex building
- Analysis of Abnormal Events and Accidents for NRL BSL 3 Facility Operation
- Emergency Preparedness and Response

Moreover, detail presentation was done on the proposed mitigation measures for each impacts for participants.

Finally, after presentation, participants acknowledged the preparation of the ESIA report and participants of the consultation meeting have raised the following concerns:

7. Implementation issues: during the construction the contractor should be monitored whether the contractors adhere the proposed mitigation and ensuring occupational safety and health.
8. Similarly, during the operation phase of the laboratory EPHI/MOH, should implement the proposed mitigation accordingly and monitor periodically for effectiveness of the proposed mitigation.
9. Occupational health and safety: The contractor is expected to follow standard occupational health and safety standards during the construction phase of the project.
10. Hazardous waste disposal: especially during the operation phase the waste should be treated and disposed according to the proposed plan and mitigation measures.

The proposed action points

- Establish mechanisms that will allow woreda sector offices to carry out follow up and monitoring of the project activities (discussion will made after the project approved by WB for arrangement)

- Ensure that the contractor carries out the construction works as per the rules, regulations and standards of the Environmental Protection Agency.
- Ensure that the NRL BSL 3 laboratory perform the laboratory works as per the standard BSL 3 laboratory procedure and waste management procedures (CDC & WHO manuals)
- Ensure that the contractor follows occupational, health and safety standards; and labour regulations in employment of his workforce.

Finally, the woreda administration representative and the sector offices under the woreda jurisdiction are willing to provide all required assistance and work with EPHI and MOH for successful implementation of this project.

List of participants of the stakeholders and Public consultation

S.N	Name	Sex	Organization	Responsibility
1.	Hassen Mohamed	M	Office for regulating law & order	Supervising Officer
2.	Endalkachew Midker	M	Office for regulating law & order	Supervising Officer
3.	Haji Siraje Mohamed	FM	Community representative	
4.	Miheret fikadu	F	Labour and Social Affairs office	Expert
5.	Mery Bela	F	Environmental Protection	Expert
6.	Hana Chekale	F	Women's Affair Office	Expert
7.	Jemanesh Kumera	F	Women's Affair Office	Expert
8.	Tomas Mesfin	M	Culture & Tourism Office	Expert
9.	Beletu Alemu	M	Health Office	Head
10.	Tsegaye Ketema	M	Community representative	
11.	Hagos Hafis	M	Community representative	
12.				
13.	Melaku Gizaw	M	EPHI	Researcher
14.	Yeabkal Daniel	M	EPHI	Researcher
15.	Dr. Eyob Abera	M	EPHI	Biosafety advisor
16.	Ahmed Mohammed	M	EPHI	Researcher

Minute of Second Community and stakeholder Consultation to disclose the BSL 3 NRL ESIA (February 28, 2019)

በኢትዮጵያ ሕብረተሰብ ጤና አገልግሎት ስለሚገኘው BSL 3 NRL ላብራቶሪ ከአካባቢው ማህበረሰብ እና ከባለድርሻ አካላት ጋር የተደገው ደይይት

አጀንዳ

በኢትዮጵያ ሕብረተሰብ ጤና አገልግሎት ስለሚገኘው BSL 3 NRL ላብራቶሪ ከአካባቢው ማህበረሰብ እና ከባለድርሻ አካላት መወያየት

ቀን: በክብር 21 ቀን 2011 በ : በኢትዮጵያ ሕብረተሰብ ጤና አገልግሎት

በክብር 21 ቀን 2011 ዓ.ም በኢትዮጵያ ሕብረተሰብ ጤና አገልግሎት (ኢ.ሕ.ጤ.አ) በተደረገው ውይይት ላይ የተሳተፉት አካላት የተውጣጡት የሀገር ሽማግሌዎች የሀይማኖት አባቶች፣ ከጉሊሊ ክ/ከተማ ወረዳ 9 የተውጣጡ ጽ/ቤቶች እንዲሁም ኢ.ሕ.ጤ.አ ባለሙያዎች ይገቡታል። ከተሳተፉት 15 ሰዎች ውስጥ 4ቱ ከኢ.ሕ.ጤ.አ ቢሆኑ የተቀሩት 11 ከወረዳ 9 የሽማግሌዎች እና ከሀይማኖት አባቶች ነበሩ።

የስብሰባው አላማ በግንባታው ግዜ እና ላብራቶሪው አገልግሎት በሚሰጥበት ግዜ ሊከሰቱ ስለሚችሉ አካባቢያዊና ማህበራዊ ተፅዕኖዎች ላይ ያላቸውን ሀሳብና አስተያየት እንዲያበረክቱ ነበር።

አቶ አዲሱ ከበደ ከብ/ላ/ላ/ግ/ዳ እንዲሁም ዶ/ር እድል አበረ የፕሮጀክቱ አስተባባሪ ስለግንባታው አላማና ጥቅም ለተሰጥሰቢያት ገለጻ አድርገዋል። ለገጻው ያተኮረው በግንባታው ወቅት ሊከሰቱ ስለሚችሉ ጉዳዮች እና መከላከያ መንገዶች ላይ ነበር።

የፕሮጀክቱ አዎንታዊ ጥቅሞች

ላብራቶሪው ስራ በሚጀምርበት ወቅት ለሕብረተሰቡ ከሚሰጥቸው ጥቅሞች መካከል፦

- የስራ ዕድል ይፈጥራል
- የበሽታዎችን ቁጥጥር ያጠነክራል
- ደረጃውን የጠበቁ የላብራቶሪ አገልግሎት በመስጠት የሕብረተሰቡን የሀይማኖት አገልግሎት ያሻሽላል

የፕሮጀክቱ አሉታዊ ጎኖች

- በከባቢ ዕድገትና አደር ላይ
- የአየር ብክለት
- የድምፅ ብክለት
- በግንባታው ስራ ተቃዋሚዎች በአካባቢው ነዋሪዎች ላይ
- የመኪና አደጋ
- የላብራቶሪ አገልግሎት መስተዳደር

ግንባታው ተጠናቆ ላብራቶሪው አገልግሎት በሚሰጥበት ወቅት የሚከሰቱ አሉታዊ ጎኖች

- በከባቢ ዕድገትና አደር ላይ

- የስራ ላይ ደህንነት
- ከላብራቶሪ ሊያመልጡ በሚችሉ አጀንቶች
- በናሙና ለያያዝና አቀማመጥ ላይ
- የላብራቶሪ ዕቃዎች ለላግባብ መጠቀም
- የአየር አደጋ
- የኪሚካል አደጋ
- የኤሌክትሪክ አደጋ
- ከቆሻሻ ማዎጣቢያ በሚወጣ የአየር ብክለት
- ተገቢ የልሀን የቆሻሻ አወገድ

ሌሎችም አሉታዊ ጎኖች መከላከያ መንገዶች ላይ ሰፊ ማህበራዊዎች ለተሳታፊዎች ተሰጥተዋል።

በመጨረሻም ተሳታፊዎቹ የሚከተሉትን ጥያቄዎች አንስተዋል።

1. በትግበራ ዙሪያ፣ በግንባታው ወቅት ከጉትራክተሩ የተቀመጡትን የመከላከያ መንገዶች መተግበሩንና የሰራተኞችን ጤና እና ደህንነት መጠበቅና ማረጋገጥ
2. በተመሳሳይ የኢ.ሕ.ጤ.አ እና የጤና ሚኒስቴር የመከላከያ መንገዶች መተግበራቸውን በወቅቱ መከታተል
3. የሰራተኞች ጤና እና ደህንነት፣ ከጉትራክተሩ የመያ ላይ ደህንነት መተግበሩን ማረጋገጥ
4. በካይ ቆሻሻ አወገድ፣ ላብራቶሪው አገልግሎት በሚሰጥበት ወቅት ቆሻሻን በተቀመጠው መመሪያ መሰረት ማስወገድ

የታቀደው የድርጊት መርህ ግብረር

- የወረዳው ጽ/ቤቶች ከትል የሚያደርጉትን መንገድ መዘርጋት
- ከጉትራክተሩ ስራው በአካባቢ ጥበቃ እጅግ ሆኖ መሰረት መተግበሩን ማረጋገጥ
- ከጉትራክተሩ የስራ ላይ ደህንነት መመሪያዎች እና ህጎች መከተሉንና መተግበሩን ማረጋገጥ
- ላብራቶሪው በCDC & WHO መሰረት ስራዎቹን መስራትን ማረጋገጥ

በመጨረሻም የወረዳ አስተዳደር ተወካዮች ጽ/ቤት ሀላፊዎች ከኢ.ሕ.ጤ.አ እና የጤና ሚኒስቴር ጋር በመሆን የፕሮጀክቱን ትግበራ ላይ አስፈላጊውን ትብብር እንደሚያደርጉ ገልጸዋል።

Community and Stakeholders Consultations Attendance Sheet for Environmental and Social Assessment for Construction of BSL 3 Reference Laboratory at Ethiopian Public Health Institute (EPHI) Federal Democratic Republic of Ethiopia Ministry of Health
Regions: Addis Ababa Sub City: Gullele Woreda: 09

S/N ተቋ	Name of Participants የተሳተፉ ሰዎች	Sex ተቋ	Organization/ማህበረሰብ መዘርጋቻ	Position/ የሕ. ድርሻ	Phone No./ ስልክ ቁጥር	Signature/ ፊርማ
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3	WELDESALEM G. A.	M	MBOS	ጽ/ቤት	09111785	[Signature]
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7	Yonas Mesfin	M	MBOS	ጽ/ቤት	0112222222	[Signature]
8	Yonas Mesfin	M	MBOS	ጽ/ቤት	0112222222	[Signature]
9	Yonas Mesfin	M	MBOS	ጽ/ቤት	0112222222	[Signature]
10	Yonas Mesfin	M	MBOS	ጽ/ቤት	0112222222	[Signature]
11	Yonas Mesfin	M	MBOS	ጽ/ቤት	0112222222	[Signature]
12	Yonas Mesfin	M	MBOS	ጽ/ቤት	0112222222	[Signature]
13	Yonas Mesfin	M	MBOS	ጽ/ቤት	0112222222	[Signature]
14	Yonas Mesfin	M	MBOS	ጽ/ቤት	0112222222	[Signature]
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Activate Windows

Minutes 3 for Community and Stakeholder Consultation for disclosure of BSL 3 ESIA

Minutes of Community and Stakeholder Consultation

(Translated from Amharic Language)

Minutes of Community and Stakeholder Consultation on waste management

Mr Adisu Kebede and Mr Gonfa Ayana from national laboratories capacity building directorate started the discussion by explaining the construction of the project in detail. The complex will have a world class BSL-3 Lab, which will be the first of its kind in the country. In addition it also has an equipment maintenance unit, a biobank and also a proficiency test preparation center. The complex is intended to serve not only Ethiopia but also for the neighboring countries.

They also discuss with the participants the documents prepared (ESIA & ICWMP) that have detail information about the expected impacts and their mitigation strategies need during the construction and operation of the project.

Ahmed Mohamed, the project team, give detail presentation on the type of waste expected during the operation of the laboratory and their treatment and disposal system .The waste generated will be:-

- ✓ Hazardous solid waste
- ✓ Non-hazardous solid waste
- ✓ Chemicals and other wastewater

The expected waste treatment and disposal techniques are:-

- ✓ Incinerator
- ✓ Septic tank with treatment plant
- ✓ Wastewater transportation to final disposal site

For the disposal of solid waste an efficient incinerator, which is odorless and smokeless will be used. The new incinerator will not have any harm on the community and the surrounding environment. The incinerate waste (ash) will be treated and disposed at Kotebe solid waste disposal site.

Wastewater generated during the operation phase will be directed into a septic tank for storage and treatment. It is equipped with UV system for the treatment of waste. In addition a regular laboratory tests will be performed to check the effectiveness of the treatment process. The treated waste will

not have any negative effect on the environment as well as the community. Finally the treated waste will be connected to the city's sewer system for final disposal.

- The participants of the community consultation raised their concerns about the effectiveness of the technology of incinerator.
- Participants meeting also recommended that during the operation phase of the BSL 3 laboratory EPHI/MOH, should implement the proposed technology of incinerator and liquid waste treatment plan.
- Participants also stated that there should be a monitoring system for waste treatment and disposal.

At the end the participants had a clear picture on the type of waste and the technologies used for the treatment and disposal of the waste from EPHI and also they understand that by using these technologies there will not be any harm on the community and the environment. The participants recognize the value of the project and want to provide anything expected from them for the implementation of the projected.

Attendance Sheet for
Stakeholders and Communities Consultations on Environmental and Social Impact Assessment for Construction
of BSL 3 National Reference Laboratory at Ethiopian Public Health Institute (EPHI)
Federal Democratic Republic of Ethiopia Ministry of Health

Regions Addis Ababa Sub City Gullele Woreda 09

Date of Consultation 2/10/2019

S.N/ ተ.ቁ	Name of Participants/ የተሳተፈ ሰዎች	Sex ፆታ	Organization/የሚሰሩበት	Position/ የስራ ድርሻ	Phone No./ ስልክ ቁጥር	Signature/ ፊርማ
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B. Annex 2: Guideline for Good Laboratory Practices, Safety and Design for BSL 3 laboratory

The containment laboratory – Biosafety Level 3 is designed and provided for work with Risk Group 3 microorganisms and with large volumes or high concentrations of Risk Group 2 microorganisms that pose an increased risk of aerosol spread. Biosafety Level 3 containment requires the strengthening of the operational and safety programmes over and above those for basic laboratories – Biosafety Levels 1 and 2. The guidelines given in this section are presented in the form of additions to those for basic laboratories – Biosafety Levels 1 and 2, which would therefore be applied before those specific for the containment laboratory – Biosafety Level 3. The major additions and changes are in:

- a. Code of practice
- b. Laboratory design and facilities
- c. Health and medical surveillance.

Laboratories in this category would be registered or listed with the national or other appropriate health authorities.

i. Code of practice for the proposed BSL3 lab

- a. The international biohazard warning symbol and sign biohazard must be displayed on the doors of the rooms where microorganisms of Risk Group 2 or higher risk groups are handled.
- b. Only authorized persons should be allowed to enter the laboratory working areas.
- c. Laboratory doors should be kept closed.
- d. Children should not be authorized or allowed to enter laboratory working areas.
- e. No animals should be admitted other than those involved in the work of the laboratory.
- f. The international biohazard warning symbol and sign displayed on laboratory access doors will identify the biosafety level and the name of the laboratory supervisor who controls access, and indicate any special conditions for entry into the area, e.g. immunization.
- g. Laboratory protective clothing will be of the type with solid-front or wrap-around gowns, scrub suits, coveralls, head covering and, where appropriate, shoe covers or dedicated shoes. Front-buttoned standard laboratory coats are unsuitable, as are sleeves that do not

fully cover the forearms. Laboratory protective clothing will not be worn outside the laboratory, and it would be decontaminated before it is laundered. The removal of street clothing and change into dedicated laboratory clothing may be warranted when working with certain agents (e.g. agricultural or zoonotic agents).

- h. Open manipulations of all potentially infectious material would be conducted within a biological safety cabinet or other primary containment device.
- i. Respiratory protective equipment may be necessary for some laboratory procedures or working with animals infected with certain pathogens.

ii. Laboratory design and facilities for the proposed BSL3 lab

The laboratory design and facilities for basic laboratories – Biosafety Levels 1 and 2 apply except where modified as follows:

- a. The laboratory will be separated from the areas that are open to unrestricted traffic flow within the building. Additional separation may be achieved by placing the laboratory at the blind end of a corridor, or constructing a partition and door or access through an anteroom (e.g. a double-door entry or basic laboratory – Biosafety Level 2), describing a specific area designed to maintain the pressure differential between the laboratory and its adjacent space. The anteroom would have facilities for separating clean and dirty clothing and a shower may also be necessary.
- b. Anteroom doors may be self-closing and interlocking so that only one door is open at a time. A break-through panel may be provided for emergency exit use.
- c. Surfaces of walls, floors and ceilings would be water-resistant and easy to clean. Openings through these surfaces (e.g. for service pipes) would be sealed to facilitate decontamination of the room(s).
- d. The laboratory room will be sealable for decontamination. Air-ducting systems will be constructed to permit gaseous decontamination.
- e. Windows will be closed, sealed and break-resistant.
- f. A hand-washing station with hands-free controls would be provided near each exit door.
- g. There would be a controlled ventilation system that maintains a directional airflow into the laboratory room. A visual monitoring device with or without alarm(s) would be installed

so that staff can at all times ensure that proper directional airflow into the laboratory room is maintained.

- h. The building ventilation system would be so constructed that air from the containment laboratory – Biosafety Level 3 is not recirculated to other areas within the building. Air may be high-efficiency particulate air (HEPA) filtered, reconditioned and recirculated within that laboratory. When exhaust air from the laboratory (other than from biological safety cabinets) is discharged to the outside of the building, it would be dispersed away from occupied buildings and air intakes. Depending on the agents in use, this air may be discharged through HEPA filters. A heating, ventilation and air-conditioning (HVAC) control system may be installed to prevent sustained positive pressurization of the laboratory. Consideration would be given to the installation of audible or clearly visible alarms to notify personnel of HVAC system failure.
- i. All HEPA filters would be installed in a manner that permits gaseous decontamination and testing.
- j. Biological safety cabinets would be sited away from walking areas and out of crosscurrents from doors and ventilation systems.
- k. The exhaust air from Class I or Class II biological safety cabinets, which will have been passed through HEPA filters, would be discharged in such a way as to avoid interference with the air balance of the cabinet or the building exhaust system.
- l. An autoclave for the decontamination of contaminated waste material would be available in the containment laboratory. If infectious waste has to be removed from the containment laboratory for decontamination and disposal, it would be transported in sealed, unbreakable and leak proof containers according to national or international regulations, as appropriate.
- m. Backflow-precaution devices would be fitted to the water supply. Vacuum lines would be protected with liquid disinfectant traps and HEPA filters, or their equivalent. Alternative vacuum pumps would also be properly protected with traps and filters.
- n. The containment laboratory – Biosafety Level 3 facility design and operational procedures would be documented.

iii. Laboratory equipment

The principles for the selection of laboratory equipment, including biological safety cabinets are the same as for the basic laboratory – Biosafety Level 2. However, at Biosafety Level 3,

manipulation of all potentially infectious material would be conducted within a biological safety cabinet or other primary containment device. Consideration would be given to equipment such as centrifuges, which will need additional containment accessories, for example, safety buckets or containment rotors. Some centrifuges and other equipment, such as cell-sorting instruments for use with infected cells, may need additional local exhaust ventilation with HEPA filtration for efficient containment.

iv. Health and medical surveillance

The objectives of health and medical surveillance programmes for basic laboratories – Biosafety Levels 1 and 2 also apply to containment laboratories – Biosafety Level 3, except where modified as follows:

- a. Medical examination of all laboratory personnel who work in containment laboratories – Biosafety Level 3 is mandatory. This would include recording of a detailed medical history and an occupationally-targeted physical examination.
- b. After a satisfactory clinical assessment, the examinee may be provided with a medical contact card stating that he or she is employed in a facility with a containment laboratory – Biosafety Level 3.

C. Annex 3: BSL 3 NRL Complex Security and Emergency response

Guidance at EPHI BSL3 lab

Traditional biosafety guidelines for laboratories have emphasized use of optimal work practices, appropriate containment equipment, well-designed facilities, and administrative controls to minimize risk of worker injury and to ensure safeguards against laboratory contamination. In recent years, concern has increased regarding use of biologic materials as agents of terrorism. Risk assessments would include reviews of the following: 1) physical security 2) security of data and electronic technology systems 3) employee security 4) access controls to laboratory 5) procedures for agent inventory and accountability 6) shipping/transfer and receiving of select agents 7) unintentional incident and injury policies 8) emergency response plans and 9) policies that address breaches in security. Therefore, for the BSL3 that will be constructed, EPHI will prepare security and emergency response plan and it would be an integral part of daily operations. All employees would be well-trained and equipped, and at least, the plan would be reviewed annually. The plans would, among other, address the following biosecurity policies and procedures (Jonathan et al.2002):

- risk and threat assessment;
- facility security plans;
- physical security;
- data and electronic technology systems;
- security policies for personnel;
- policies regarding accessing the laboratory;
- specimen accountability;
- receipt of agents into the laboratory;
- transfer or shipping of select agents from the laboratory;
- emergency response plans; and
- reporting of incidents, unintentional injuries and security breaches.

Definitions

Threat assessment: A judgment, based on available information, of the actual or potential threat of malevolent action.

Vulnerability: An exploitable capability, security weakness, or deficiency at a facility. Exploitable capabilities or weaknesses are those inherent in the design or layout of the biologic

laboratory and its protection, or those existing because of the failure to meet or maintain prescribed security standards when evaluated against defined threats.

Vulnerability assessment: A systematic evaluation process in which qualitative and quantitative techniques are applied to arrive at an effectiveness level for a security system to protect biologic laboratories and operations from specifically defined acts that can oppose or harm a person's interest.

1. Risk Assessment

Recommendation: EPHI will conduct a risk assessment and threat analysis of the BSL3 lab as a precursor to the security plan.

Background: A threat analysis, the first step in determining risk, identifies and evaluates each threat on the basis of different factors (e.g., the capability and intent to attack an asset, the likelihood of a successful attack, and the attack's probable lethality). Risk management is the deliberate process of understanding risk (i.e., the likelihood that a threat will harm an asset with certain severity of consequences) and deciding on and implementing actions to reduce that risk. Risk management principles are based on acknowledgment that: 1) although risk usually cannot be eliminated, it can be reduced by enhancing protection from validated and credible threats, 2) although threats are possible, certain threats are more probable than others and 3) all assets are not equally critical. Therefore, each facility would implement certain measures to enhance security regarding select agents. EPHI BSL3 lab would conduct a risk assessment and threat analysis of its assets and select agents. The threat would be defined against the vulnerabilities of the laboratory to determine the necessary components of a facility security plan and system.

The risk assessment would include a systematic approach in which threats are defined and vulnerabilities are examined; risks associated with those vulnerabilities are mitigated with a security systems approach. EPHI would ensure the security plan includes collaboration between senior management, scientific staff, human resource officials, information technology (IT) staff, engineering officials and security officials. This coordinated approach is critical to ensuring that security recommendations provide a reasonable and adequate assurance of laboratory security without unduly impacting the scientific work.

2. Facility Security Plans for EPHI BSL3 Lab

Recommendation: EPHI will establish the BSL3 lab security plan.

EPHI will develop a comprehensive security plans addressing: physical security, data and IT system security, security policies for personnel, policies for accessing select agent areas, specimen accountability, receipt of select agents into the laboratory, transfer or shipping of select agents from the laboratory, emergency response plans, and reporting of incidents, injuries and breaches. Based on the risk assessments, EPHI would develop security policies. Security plans would include measures that address physical security of building and laboratory areas. Policies would also address concerns associated with access, use, storage, and transfer of sensitive data. If sensitive electronic data are present, IT specialists will assess the security of hardware and software products in addition to the security of local area networks.

At least annually, EPHI will review safety, security and IT policies and procedures for consistency and applicability. These procedures would also be reviewed after any incident or change in regulations. Necessary changes would be incorporated into the revised plans and communicated to all. Laboratory supervisors would ensure that all laboratory workers and visitors understand security requirements and that all employees are trained and equipped to follow established procedures. The security plan would be an integral part of daily operations. New employees would receive training when they first begin work, and all employees would receive training at least annually thereafter. Training would be updated as policies and procedures change. All training would be documented by maintaining records of training schedules and employee attendance. Security plans would receive periodic performance testing to determine their effectiveness. Test procedures can vary from a simple check of keys, locks and alarms to a full-scale laboratory or facility exercise.

3. Security Policies for EPHI BSL3 lab Personnel

Recommendation: EPHI will establish security-related policies for all personnel working in the BSL3 lab. The BSL3 lab administrators would be familiar with all laboratory workers. EPHI would also establish a policy for screening employees who require access to select agent areas to include full- and part-time employees, contractors, emergency personnel and visitors. Additional screening might be necessary for employees who require access to other types of sensitive or secure data and work areas. These screening procedures will commensurate with the sensitivity of the data and work areas (e.g., federal security clearances for government employees and contractors). EPHI will also ensure that all workers approved to get access to select agents (e.g., students, research scientists and other short-term employees) wear visible identification badges that include a

photograph, wearer's name and an expiration date. The lab administrators would consider using easily recognizable marks on the identification badges to indicate access to sensitive or secure areas.

4. EPHI BSL3 Lab Access Control

Recommendation: EPHI would strictly control access to areas where selected agents are used or stored. By taking different measures, including:

- Consolidating laboratory work areas to implement security measures more effectively.
- Separating selected agent areas from the public areas of the buildings.
- Locking all select agent areas when unoccupied.
- Using keys or other security devices to permit entry into these restricted areas.

Methods of secure access and monitoring controls can include key or electronic locking pass keys, combination keypad, use of lock-boxes to store materials in freezers or refrigerators, video surveillance cameras, or other control actions. In addition, protocols for periodically changing combination keypad access numbers would be developed for maximum protection. Again, regular inspections will be conducted for graded levels of security protection on the basis of site-specific risk and threat analysis. This security can be accomplished through card access systems, biometrics, or other systems that provide restricted access. This would also involve:

- Locking all freezers, refrigerators, cabinets, and other containers where select agents are stored when they are not in direct view of a laboratory worker.
- Limiting access to select agent areas to authorized personnel. All others entering select agent areas must be escorted and monitored by authorized personnel.
- Recording all entries into these areas, including entries by visitors, maintenance workers, service workers, and others needing one-time or occasional entry.
- Limiting routine cleaning, maintenance, and repairs to hours when authorized employees are present and able to serve as escorts and monitors.
- Establishing procedures and training for admitting repair personnel or other contractors who require repetitive or emergency access to select agent areas.
- Ensuring visitors are issued identification badges, including name and expiration date, and escorted and monitored into and out of select agent areas. Such visits would be kept to a minimum.

- Ensuring procedures are in place for reporting and removing unauthorized persons. These procedures would be developed through collaboration among senior scientific, administrative, and security management personnel. These procedures would be included in security training and reviewed for compliance at least annually.

5. Select Agent Accountability

Recommendation: EPHI would establish a system of accountability for select agents. A procedure to ensure adequate control of select agents and maintain up-to-date inventory of seed stocks, toxins, and agents in long-term storage would be established. Records would include data regarding the agent's location, use, storage method, inventory, external transfers (sender/receiver, transfer date, and amount), internal transfer (sender/receiver, transfer date, amount), further distribution, and destruction (method, amount, date, and a point of contact). It will also establish procedures that maintain accurate and up-to-date records of authorizations for entry into limited access areas (i.e., a current list of persons who possess door keys and those who have knowledge of keypad access numbers or the security system).

6. Receiving Select Agents at EPHI BSL3 lab

Recommendation: EPHI will develop procedures for bringing select agent specimens into the laboratory. A centralized receiving area for select agents is recommended to maximize safety and minimize security hazards associated with damaged or unknown packages. The BSL3 lab would establish procedures for inspecting all packages (i.e., by visual or noninvasive techniques) before they are brought into the laboratory area. Suspicious packages would be handled as prescribed by federal and Addis Ababa law enforcement agencies. Biologic safety cabinet or other appropriate containment device would be used when opening packages containing specimens, bacterial or virus isolates, or toxins. Packages would be opened by only trained and authorized personnel.

7. Transfer or Shipping of Select Agents

Recommendation: EPHI would develop procedures for transferring or shipping select agents from the laboratory. EPHI would adopt package, label, and transport select agents in conformance with all applicable local, federal, and international transportation and shipping regulations. Materials that are transported by airline carrier would also comply with packaging and shipping regulations set by the International Air Transport Association (IATA). Personnel who pack,

handle, and ship these agents (including import and export) would be subject to all applicable training. The responsible facility official would be notified of all select agent transfers, internal or external. EPHI would ensure that required permits (e.g., granted by the pertinent Ethiopian environmental and health regulatory organs and IATA) are obtained before select agents are prepared for transport. Standard operating procedures would be in place for import and export activities. Contaminated or possibly contaminated materials would be decontaminated before they leave the laboratory area. Avoid hand-carrying select agents when transferring them to other external facilities. If select agents are to be hand carried on common carriers, all applicable packaging, transport, and training regulations would be followed. EPHI would develop and follow a protocol for intra-facility transfer of all select agents.

8. Emergency Response Plans

Recommendation: EPHI would develop and integrate laboratory emergency plans with facility wide plans. These plans would also include such adverse event assessments as bomb threats, severe weather (e.g floods, earthquakes, power outages, and other natural or man-made disasters). While developing the plans, EPHI would include the BSL3 administrators, scientific directors, principal investigators, laboratory workers, maintenance and engineering support staff, facility safety officers, and facility security officials in emergency planning. Include provisions for immediate notification of and response by laboratory directors, laboratory workers, safety office personnel, or other knowledgeable persons when an emergency occurs. EPHI BSL3 will establish advance coordination with local police, fire, and other emergency responders to assist community emergency responders in planning for emergencies in select agent laboratory and animal areas. Discussion would address security concerns associated with sharing of sensitive information regarding secure work areas. Consider circumstances that might require the emergency relocation of select agents to another secure location. Reevaluate and train employees and conduct exercises of the emergency response plan at least annually.

9. Incident Reporting

Recommendation: EPHI would establish a protocol for reporting adverse incidents. It would also ensure that the BSL3 laboratory administrators, in cooperation with facility safety, security, and public relations officials, have policies and procedures in place for reporting and investigating

unintentional injuries, incidents (e.g., unauthorized personnel in restricted areas, missing biologic agents or toxins, and unusual or threatening phone calls), or breaches in security measures. Pertinent environmental and health regulatory organs in Ethiopia would be notified immediately if select agents are discovered to be missing, released outside the laboratory, involved in worker exposures or infections, or misused. Additionally, all incidents involving select agents (e.g., occupational exposure or breaches of primary containment) would be reported to local public health authorities.

D. Annex 4: List of Agents and Selected Toxins in Ethiopia

	Bacteria	Remarks
1	<i>Bacillus anthracis</i>	
2	<i>Botulinum neurotoxin producing species of Clostridium</i>	
3	<i>Brucella spp. (Brucella melitensis, Brucella abortus and Brucella suis)</i>	Spp. Specified
4	<i>Burkholderia mallei</i>	
5	<i>Burkholderia pseudomallei</i>	
6	<i>Campylobacter jejuni & coli (the causes of gastro-enteritis in animals & humans)</i>	Newly added May 27
7	<i>Clostridium spp (Cl. Chauvoei(Blackleg) , Cl . Perfringens, Clostridium tetani)</i>	More spp. added
8	<i>Coxiella burnettii</i>	
9	<i>E.coli O157: H7 (Verocytotoxigenic Escherichia coli)</i>	Newly added May 27
10	<i>Francisella tularensis</i>	
11	<i>Leptosporiasis spp</i>	
12	<i>Listeria spp.</i>	
13	<i>Methicillin-resistant Staphylococcus aureus</i>	Newly added May 27
14	<i>Mycobacterium Bovis</i>	Newly added May 27
15	<i>Mycobacterium tuberculosis - MDR</i>	
16	<i>Mycoplasma mycoides subspecies mycoides (small colony)</i>	Name corrected
17	<i>Mycoplasma mycoides subspecies mycoides SC</i>	
18	<i>Mycoplasma mycoides subspecies Capri Pnuemoniae</i>	Name corrected
19	<i>P. Manhemia hemolytic</i>	
20	<i>Salmonella spp.</i>	
21	<i>Shigella spp.</i>	
22	<i>Streptococcus agalactia (Mastitis clinical and sub clinical)</i>	Newly added
23	<i>V.cholera</i>	Newly added May 27
24	<i>Yersinia pestis</i>	
	Virus	
1	<i>African horse sickness virus</i>	Newly added May 27
2	<i>African swine fever virus</i>	
3	<i>Blue Tongue virus (BTV)</i>	
4	<i>Bovine Herpes Virus 1(BHV-1)</i>	
5	<i>Bovine viral Diarhoe virus(BVDV) (pest virus)</i>	Newly added May 27
6	<i>Camel pox Virus</i>	Newly added May 27
7	<i>Classical swine fever virus</i>	
8	<i>Crimean-Congo haemorrhagic fever virus</i>	
9	<i>Ebola virus (EBOV)</i>	
10	<i>Equine herpes virus</i>	Newly added May 27

11	<i>Foot and mouth disease virus</i>	
12	Fowl pox virus	Newly added May 27
13	<i>Gallid herpes virus 2 (GaHV-2)</i>	
14	<i>Hendra virus</i>	
15	<i>Highly pathogenic avian influenza (HPAI)</i>	
16	<i>Infectious bursal disease virus (IBDV)</i>	
17	<i>Lassa fever virus</i>	
18	<i>Lugo virus</i>	
19	<i>Lumpy skin disease virus (Neethling virus)</i>	Name corrected
20	<i>Marburg virus</i>	
21	<i>Marek's disease virus (Herpes virus of chicken)</i>	Newly added May 27
22	MERS-COV	Newly added May 27
23	<i>Monkeypox virus</i>	
24	<i>Newcastle disease virus</i>	
25	<i>Omsk hemorrhagic fever virus</i>	
26	<i>Parapox virus(Orf virus)</i>	
27	<i>Peste des petitis ruminants virus</i>	
28	<i>Poliovirus</i>	
29	<i>Rabies virus</i>	
30	<i>Rift Valley fever virus</i>	
31	<i>Rinderpest virus</i>	
32	<i>SARS associated coronavirus (SARS – CoV)</i>	
33	<i>Sheep pox virus,goat pox virus and (Capripox)</i>	
34	<i>Variola major virus (Smallpox)</i>	Newly added May 27

Toxins

		<i>Amount allowed to transport</i>
1	<i>Abrin</i>	<i>100 mg</i>
2	<i>Aflatoxins</i>	
3	<i>Botulinum neurotoxin</i>	<i>0.5 mg</i>
4	<i>Cholera toxin</i>	
5	<i>Clostridium perfringens alpha, beta 1, beta 2, epsilon and iota toxins</i>	
6	<i>Ochratoxin A</i>	
7	<i>Ricin</i>	<i>100 mg</i>
8	<i>Saxitoxin</i>	<i>100 mg</i>
9	<i>Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxins (formerly known as Staphylococcus enterotoxin F)</i>	<i>5 mg</i>
10	<i>T-2 Toxin</i>	<i>1000 mg</i>
11	<i>Tetrodotoxin</i>	<i>100 mg</i>
12	<i>Shiga toxin</i>	

E. Annex 5: Inspection Checklist for BSL-3 Laboratories (BMBL 5th Edition)

Statement	Response			Comments
	Yes	No	N/A	
The laboratory supervisor must enforce the institutional policies that control access to the laboratory.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Mouth pipetting is prohibited; mechanical pipetting devices must be used.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Precautions, including those listed below, must always be taken with sharp items. These include:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Plasticware should be substituted for glassware whenever possible.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Perform all procedures to minimize the creation of splashes and/or aerosols.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

F. Annex 6: List of ESIA Preparers

List of Contributor Experts

1. **Eyob Abera**, (MSc, MPH, PhD) Advisor, Biosafety and Biosecurity, Laboratory Quality System and public health expert, Ethiopian Public Health Institute, Addis Ababa, Ethiopia.
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3. **Yeabkal Daniel**, (BSc, MSc) Assistance researcher, Biosafety and Biosecurity expert
4. **Abel Weldetinsae**, (BSc, MSc) Associate researcher, Environmental pollution and sanitation expert, Ethiopian Public Health Institute, Addis Ababa, Ethiopia.
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7. **Melaku Gizaw**, (BSc, MSc), Associate researcher, Environmental analytical chemist, Ethiopian Public Health Institute, Addis Ababa, Ethiopia.
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11. **Zereu Girmay**, (BSc, MSc), General Manager and Lead Consultant, ZG Environment Consultancy, Addis Ababa, Ethiopia.
12. **Asefa Addisu, (BA)**, Senior Social Development Consultant, ZG Environment Consultancy, Addis Ababa, Ethiopia.

G. Annex 7: EPHI Specification requirement for Incinerator

Type	Pyrolytic- Hot Medical Waste Disposing Machine																		
Technology	Pyrolytic																		
Operation Condition	8-16 Hr /day																		
Controls	Built in data recording																		
Incinerator /Primary Combustion Chamber	Type: continuous loading																		
	Capacity/Burn rate per hour 50 kg/hr																		
	Temperature: ≥ 900 °C																		
	Material: External- 3 layers Internal lining: a fire proof material of pre-fired refractory bricks with Aluminium lining, resistant to corrosive waste or gas and to thermal shock																		
Secondary Combustion Chamber	Type: horizontal/vertical																		
	Temperature: ≥ 1200 °C																		
	Residence time of gases : ≥ 2 seconds																		
	Material External- Low thermal mass insulation 14-30 °C Internal lining: a fire proof material of pre-fired refractory bricks with Aluminium nettle lining, resistant to corrosive waste or gas and to thermal shock.																		
Burner system	auxiliary burners (for start-up and close-down operations), High turbulence of exhaust gases and reduction of air excess: e.g. injection of secondary air or recirculated flue gas, preheating of the air streams, regulated air inflow																		
Ash Handling System	Both Automatic and manual removal of Ash. Must ensure removal/treatment of hazardous remnants of ash.																		
Flue gas treatment system	Capable of treating the flow of flue gas as the incinerator is operating at its maximum capacity																		
	Auxiliary device: Water level gauge, pressure sensor, PH sensor..etc																		
	Auxiliary device: Fuel cutoff device																		
Waste feeding mechanism	Automatic pneumatic/hydraulic waste loading system or conveyor belt , capacity > 650L at a time																		
Chimney (Stack)	Type: Vertical type																		
	height: ≥ 7 meter																		
	Material: Fireproof cast, stainless steel																		
Wet scrubbing system	Vertical sprat tower with baffles or packing inside																		
Gas emission	Reduction of Pollutant gas SO ₂ , HCL, HF and line particulate that meet WBG/EU requirement including the other emissions																		
Emission control device	The emission reduction device control (Fabric filter coated with catalyst) made from PTFE, with parallel dedusting, lower contamination of filter dusts to PCDD/PCDF destruction at the catalytic surface that have high efficiency reduction of dioxin upto <0.1 ng TEQ/m ³																		
OUTPUT	ASH -Max $\leq 5\%$ of original waste size																		
	GAS- SMOKELESS,ODORLESS																		
Emission standard	WB emission standards as follow: <table style="width: 100%; border-collapse: collapse;"> <tr> <td>Total Particulate Matter (PM)</td> <td style="text-align: right;">10 mg/Nm³</td> </tr> <tr> <td>Total organic carbon (TOC)</td> <td style="text-align: right;">10 mg/Nm³</td> </tr> <tr> <td>Hydrogen chloride (HCl)</td> <td style="text-align: right;">10 mg/Nm³</td> </tr> <tr> <td>Hydrogen fluoride (HF)</td> <td style="text-align: right;">1mg/Nm³</td> </tr> <tr> <td>Sulfur dioxide (SO₂)</td> <td style="text-align: right;">50 mg/Nm³</td> </tr> <tr> <td>Carbon monoxide (CO)</td> <td style="text-align: right;">50 mg/Nm³</td> </tr> <tr> <td>NO_x</td> <td style="text-align: right;">200 mg/Nm³</td> </tr> <tr> <td>Mercury (Hg)</td> <td style="text-align: right;">0.05 mg/Nm³</td> </tr> <tr> <td>Cadmium + Thallium (Cd + Tl)</td> <td style="text-align: right;">0.05 mg/Nm³</td> </tr> </table>	Total Particulate Matter (PM)	10 mg/Nm ³	Total organic carbon (TOC)	10 mg/Nm ³	Hydrogen chloride (HCl)	10 mg/Nm ³	Hydrogen fluoride (HF)	1mg/Nm ³	Sulfur dioxide (SO ₂)	50 mg/Nm ³	Carbon monoxide (CO)	50 mg/Nm ³	NO _x	200 mg/Nm ³	Mercury (Hg)	0.05 mg/Nm ³	Cadmium + Thallium (Cd + Tl)	0.05 mg/Nm ³
Total Particulate Matter (PM)	10 mg/Nm ³																		
Total organic carbon (TOC)	10 mg/Nm ³																		
Hydrogen chloride (HCl)	10 mg/Nm ³																		
Hydrogen fluoride (HF)	1mg/Nm ³																		
Sulfur dioxide (SO ₂)	50 mg/Nm ³																		
Carbon monoxide (CO)	50 mg/Nm ³																		
NO _x	200 mg/Nm ³																		
Mercury (Hg)	0.05 mg/Nm ³																		
Cadmium + Thallium (Cd + Tl)	0.05 mg/Nm ³																		

	Sb, As, Pb, Cr, Co, Cu, Mn, Ni and V 0.5 mg/Nm ³ Polychlorinated dibenzodioxin and dibenzofuran (PCDD/F) 0.1 Ng/Nm ³ TEQ <i>Notes: Oxygen level for incinerators is 7 percent</i>
Test report for emission testing	Must be provided
Additional Requirement	<ul style="list-style-type: none"> - Local agent or branch in Ethiopia - Training for users as well as for EPHI maintenance staff on preventive maintenance - Fuel tanker with a minimum capacity of 2500 litre (material type need to be specified) - The bidder should be willing to sign at least a five years' service and maintenance agreement with the client (EPHI)

Description: Incinerator should be smokeless, odourless combustion and it should be made by high-quality cast, insulation, and steel plate as well as minimum generation of dust. Moreover the incinerator should be corrosion resistant.

Item No	EPHI minimum technical requirements	Is Bid compliant? Bidder to complete	Details of goods offered. Bidder to complete
	Type of incinerator : Pyrolytic – hot medical waste disposing machine	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Operation Condition: 8-16 hr/ day	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Control: Built-in data recording	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Refractory temperature resistance Primary Chamber: 1300 °C - 1600 °C Secondary Chamber: 1400 °C - 1600 °C	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Incinerator /Primary Combustion Chamber	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Operating temperature: Primary Chamber: 900 – 1200 °C	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Type: continuous loading	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Capacity/Burn rate per hour:> 50 kg/hr	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Material: External- 3 layers Internal lining: a fire proof material of pre-fired refractory bricks with Aluminium lining, resistant to corrosive waste or gas and to thermal shock	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Secondary Combustion Chamber	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Type: horizontal/vertical	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Temperature: ≥1200- 1300 °C	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Residence time of gases : ≥2 seconds	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable

	Ash Residue: $\leq 5\%$ of original waste size	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Ash Handling System: Both Automatic and manual removal of Ash. Must ensure removal/treatment of hazardous remnants of ash	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Flue gas treatment system : Capable of treating the flow of flue gas as the incinerator is operating at its maximum capacity	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Auxiliary device: Water level gauge, pressure sensor, PH sensor..etc	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Auxiliary device: Fuel cut-off device	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Waste feeding mechanism: Automatic pneumatic/hydraulic waste loading system or conveyor belt , capacity $> 650L$ at a time	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Chimney (Stack): Type: Vertical type height: ≥ 7 meter' Material: Fireproof cast, stainless steel	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	OUTPUT: GAS- SMOKELESS,ODORLESS	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	ASH -Max $\leq 5\%$ of original waste size	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Reduction of Pollutant gas SO ₂ , HCL, HF and line particulate	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Emission standard: WHO/ European	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Test report for emission testing provided?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Heat exchange mode: Automatic	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Accessories: All standard accessories for incinerator, including but not limited to loading system, heat exchangers, pollution control system, ash removal system, including ladder and oil tanker (2500litre capacity).	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Operating Environment: The incinerator is capable to operate at the altitude of 2400mt above sea level. (according to the site conditions)	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Power Requirement: 220 Vac single phase or 380 Vac three phase 4 wire system 50HZ	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Installation Testing and Commissioning : to be conducted by certified or qualified personnel.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Supplier shall provide the following documentation User (Operating) manual in English. Service (Technical / Maintenance) manual in English. Certificate of calibration and inspection from factory.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable

	Fast moving spare parts: Supplier is able to provide fast moving spare parts with quantities as described in the price schedule or their equivalent.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Training: Supplier is able to provide training on operation, management and maintenance of incinerators.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Warranty Comprehensive warranty for minimum 2 year.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Maintenance Service during Warranty Period During warranty period supplier must ensure, corrective/breakdown maintenance whenever required.	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	Supplier has a local agent or branch office in Ethiopia (please indicate the name and contact details of the agent)	<input type="checkbox"/> Yes <input type="checkbox"/> No	Insert details of goods offered, including specifications and brand/model offered if applicable
	<p>Able to provides all necessary information that would be used as an input for preparation of floor (platform) and room for the incinerator to be supplied such as the following;</p> <p>Lay outs (drawings) and pictures of the incinerators to be installed</p> <p>Length, width and height of incinerator, Area (length x width) for the floor (platform) and Length, width and height for roofing, for each type of incinerators to be installed</p> <p><i>Needs during the transport, installation, assembly, commissioning and operation of the equipment in terms of access points, available space to operate (inside and outside of the room), ways to get to the site where the equipment will be placed or any others. ;</i></p> <p><i>Technical Specifications (fuel consumption rate, weight, anchoring system, support points, etc.);</i></p> <p><i>Chimney specifications to be used for the roof design (size, support needs, insulation);</i></p> <p><i>Considerations related to operation and Maintenance, for e.g., minimum available area to perform routine maintenance tasks and replacement of key parts that need to be changed more frequently;</i></p> <p><i>Any consideration/need of the incinerator while being operated that might impact the design of the room/shelter where it will be placed.</i></p> <p><i>Other important information to be considered that can influence or impact the designing and building processes of the infrastructure for the incinerators, for example area dimension for other accessory parts like fuel tanker storage, if applicable, etc....</i></p>		Insert details of goods offered, including specifications and brand/model offered if applicable

H. Annex 8: Some of the EPHI Laboratory Accreditation Certificates



ETHIOPIAN NATIONAL ACCREDITATION OFFICE

ACCREDITATION CERTIFICATE

**Ethiopian Public Health Institute
Food Science and Nutrition Laboratory
Addis Ababa
Ethiopia**
Facility Accreditation No: T0022

is accredited by the Ethiopian National Accreditation Office (ENAO) to perform tests in accordance with the attached *Scope of Accreditation* in the field of

Chemical testing

The facility is accredited in accordance with the requirements of ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*. The accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system. While this certificate remains valid, the Accredited Facility named above is authorized to use the relevant ENAO accreditation symbol to issue test reports and/or certificates.

Effective Date: 06 October 2016
Certificate Expires: 05 April 2021

Ato Araya Fisseha
Director General
Ethiopian National Accreditation Office



ETHIOPIAN NATIONAL ACCREDITATION OFFICE

ACCREDITATION CERTIFICATE

**Ethiopian Public Health Institute
Clinical Bacteriology and Mycology Reference Laboratory
Addis Ababa
Ethiopia**
Facility Accreditation No: M0026

Issue No: 01

is accredited by the Ethiopian National Accreditation Office (ENAO) to perform tests in accordance with the attached *Scope of Accreditation* in the field of

Medical Testing

The facility is accredited in accordance with the requirements of ISO 15189:2012, *Medical laboratory Requirements for Quality and competence*. The accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system. While this certificate remains valid, the Accredited Facility named above is authorized to use the relevant ENAO accreditation symbol to issue test reports and/or certificates.

Effective Date: July 10, 2017
Certificate Expires: January 9, 2022

Ato Anya Fesseha
Director General
Ethiopian National Accreditation Office

Page 1 of 2



December 26, 2017

In reply refer to: ETH/WR/EPH/2384/2017

Honourable State Minister,

Subject: Accreditation of EPH National Polio Laboratory

I have the honor to inform Your Excellency that the detection and laboratory evaluation of acute flaccid paralysis are key components for certification of polio eradication for all countries. Test results are accepted only from a WHO accredited Poliovirus laboratory.

In this regard, accreditation of polio laboratories is reviewed annually by WHO and is based on laboratory performance during the preceding 12 months with complete data, using a set of WHO core performance criteria. Accreditation is given for the upcoming calendar year and provides documentation that a laboratory performing intra-typic differentiation (ITD) of polio viruses has the capability and the capacity to detect and identify the serotype and /or type of polioviruses that may be present in any specimen, promptly report wild polioviruses and refer such isolates as well as polioviruses with discordant results to a sequencing laboratory for genetic characterization.

This is, therefore, to inform that the annual polio laboratory accreditation process was conducted in March 2017. The laboratory attained accreditation standards and will thus be fully accredited for 12 months from the date of review. WHO will continue to provide the necessary assistance to maintain the required standard polio laboratory performance. Please refer to the attached detailed report of the accreditation for your reference.

Please accept, Sir, the assurance of our highest consideration.

Sincerely yours,

H.E. Dr. Ferede Worku
Honourable State Minister
Federal Ministry of Health
Addis Ababa

H.E. Dr. Ferede Worku
Honourable State Minister
Federal Ministry of Health
Addis Ababa

cc: Dr. Eshel Abate
Director General
EPHI
Addis Ababa



Presented to the
**Ethiopian Public Health Institute,
Clinical Bacteriology and Mycology
Reference Laboratory**

by the
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for successful completion of the ASM Microbiology Mentoring Program.

This laboratory has demonstrated the ability to perform effectively the core functions and activities of a microbiology reference laboratory on this day, 21 of September 2017.



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Chief Executive Officer, ASM



I. Annex 9: General Procedures for Spill Cleanup

1. Determine the nature and the extent of the spill—what has been spilled (i.e., the chemical or biological agent), its concentration, quantity, and location.
2. Evacuate the area immediately (if necessary to prevent exposure of additional persons to a particularly toxic or virulent agent).
3. Provide immediate medical treatment to those exposed (if warranted by the nature of the exposure).
4. Secure and post the spill area to prevent additional exposures and spread of the spill.
5. Put on appropriate personal protective equipment (PPE).
 - a. Always: glasses, gloves, lab coat or apron, shoe coverings.
 - b. As appropriate (depending on the nature of the spill): face shield or goggles, respirator, boots.
6. Contain the spill (e.g., by dyking or ringing with absorbent material).
7. Decontaminate the spilled material if warranted (i.e., it is often prudent to decontaminate the spilled material before it is picked up). Disinfect using 10% bleach solution or another approved disinfectant (see section 10.6) for a thirty-minute contact time.
8. Pick up the spilled material:
 - A. Solids:
 - Pick up by mechanical means (e.g., pan and brush, forceps).
 - Discard as medical, hazardous, or radioactive waste as appropriate.
 - B. Liquids:
 - Absorb the spill with absorbent material as appropriate (e.g., paper towels, vermiculite).
 - Discard as medical, hazardous, or radioactive waste as appropriate.
 - C. Broken glass and other sharps:
 - Pick up by mechanical means (e.g., forceps, pan and brush), never by hand.
 - Dispose as sharps.
9. Decontaminate the area using an appropriate disinfectant (see Section 10.6).
10. Rinse/clean the area (if necessary) and absorb and collect waste materials.
11. Dispose of collected material and cleanup materials as medical, hazardous, or radioactive waste as appropriate.
12. Decontaminate reusable items (such as dust pans, brushes, forceps).
13. Remove personal protective equipment (PPE).
 - a. Discard disposable items as medical, hazardous, or radioactive waste as appropriate.

- b. Decontaminate reusable items (such as heavy rubber gloves, boots, aprons, gowns) before cleaning or laundering.
- 14. Wash all exposed skin thoroughly.
- 15. Perform medical treatment and follow up as appropriate for the particular type of material.

J. Annex 10: Guidelines for Management of Each Class of HCW

See the definition and classification of Healthcare Waste in Ethiopia chapter five section 5.3

Class 1: Non-risk HCW

- Class 1 non-risk HCW shall be placed in black containers.
- Containers should be placed in all rooms, 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 then 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.
- Non-infectious 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 liquid waste treatment plant 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 shall be drained to the liquid waste treatment plant 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

K. Annex 11: 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.

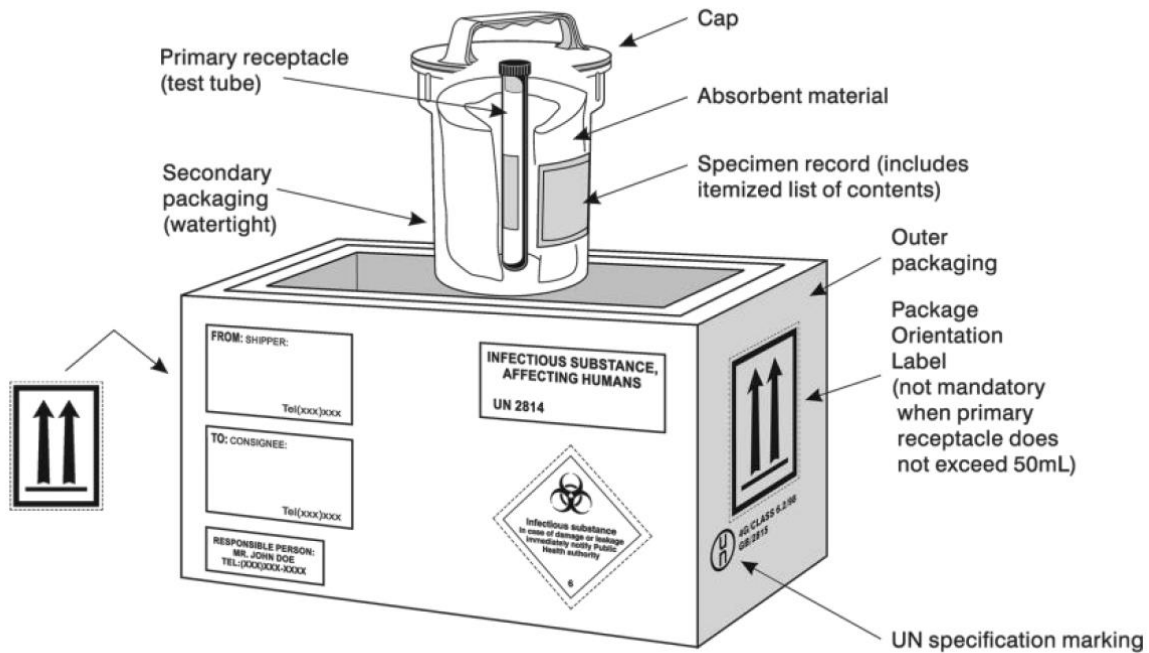


Figure 1. Example of triple packaging system for the packaging and labelling of Category A infectious substances

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

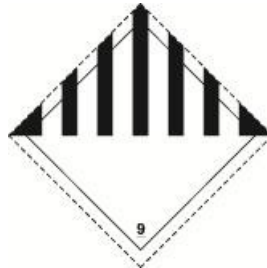


Figure 3 . Hazard label for certain noninfectious genetically modified microorganisms and organisms (UN 3245) and for carbon dioxide, solid (dry ice) (UN 1845); substances packed in dry ice (see section on Refrigerants) shall bear this label in addition to the primary risk label (e.g. the label shown 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 Beautycity Nicosounty			Air Waybill No. 543 7654 9876 Page 1 of 1 Pages Shipper's Reference Number (optional)			
Consignee Dr AB Normal, tel 03210 987 4568 Virobactung Laboratories 6 Many Way 98765 Myplace Hercounty						
Two completed and signed copies of this declaration must be handed to the operator.			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.			
TRANSPORT DETAILS This shipment is within the limitations prescribed for: (Delete non-applicable) <input checked="" type="checkbox"/> PASSENGER AND CARGO AIRCRAFT <input type="checkbox"/> AIRCRAFT <input type="checkbox"/> RAIL <input type="checkbox"/> ROAD <input type="checkbox"/> SEA			Airport of Departure: Amleaving			
Airport of Destination Willgetthere			Shipment Type (Delete non-applicable) <input type="checkbox"/> NON-RADIOACTIVE <input checked="" type="checkbox"/> 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: Beautycity 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.

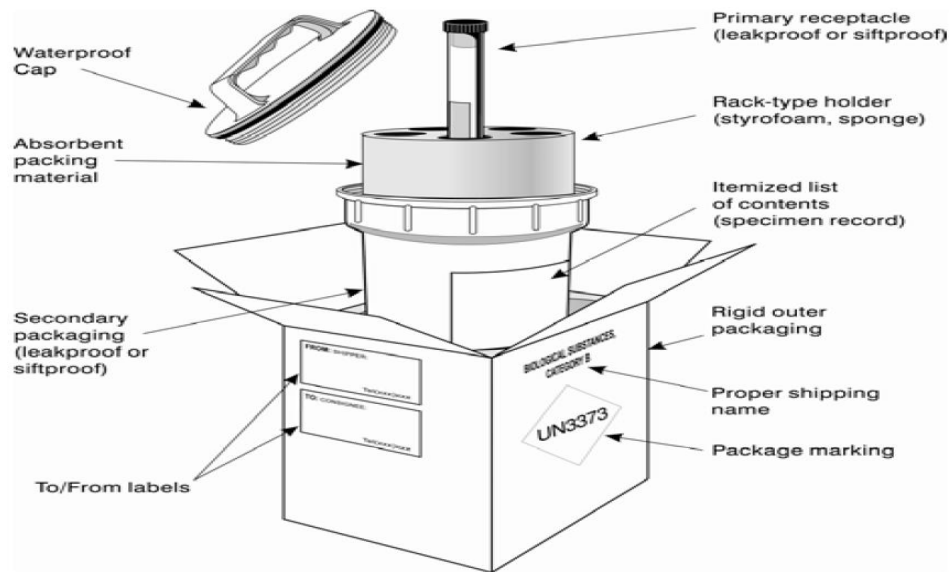


Figure 5: Example of the triple packaging system for the packing and labelling Category B infectious substances (adopted from WHO)

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 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:

4. Wear gloves and protecting clothing, including face and eye protection if indicated.

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.
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 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 6.3.5.2 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.