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### **III. List of Abbreviations**

ACRIFP	Africa CDC Regional Investment Financing Program
ACRIFPF	Africa CDC Regional Investment Financing Program Fund
BSL	Biosafety Level
EPHI	Ethiopian Public Health Institute
AMR	Antimicrobial Resistance
BSC	Biosafety Cabinet
BSL	Biosafety Level
CDC	Centre for Diseases Prevention and Control
EOC	Emergency Operating Centre
EPHI	Ethiopian Public Health Institute
ESIA	Environmental and Social Impact Assessment
ESMP	Environmental and Social Management Plan
FDRE	Federal Democratic Republic of Ethiopia
FEPA	Federal Environmental Protection Authority
FEPA	Federal Environmental Protection Authority
FEPA	Federal Environmental Protection Agency
FFECCC	Federal Forest Environmental and Climate Change Commission
FMOH	Federal Ministry of Health
GoE	Government of Ethiopia
GTP	Growth and Transformation Plan
HCF	Health Care Facility
HCW	Health Care Waste
HCWNG	Healthcare Waste Management National Guideline
HF	Health Facility
HIV	Human Immunodeficiency Virus
HSDP	Health Sector Development Plan
HWMNG	Healthcare Waste Management National Guideline
HWMP	Health Waste Management Plan
ICWMP	Infection Control and Waste Management Plan
IPPS	Infection Prevention and Patient Safety
LEMC	Laboratory Equipment Maintenance Centre
MDG	Millennium Development Goals
MOH	Ministry of Health

NDMC	National Data Management Centre
NRL	National Reference Laboratory
OSHA	Occupational Safety and Health Administration
PHEM	Public Health Emergency Management
PHEM	Public Health Emergency Management
PHID	Public Health Infrastructure Directorate
PPSD	Project Procurement Strategy for Development
PT	Proficiency Testing
PTPC	Proficiency Testing Panel Production Centre
PVC	Polyvinylchloride
RHB	Regional Health Bureau
RHB	Regional Health Bureau
SNNPRS	Southern Nations, Nationalities, and People's Regional State
TB	Tuberculosis
UV	Ultra Violet
WB	World Bank
WBG	World Bank Group
WHO	World Health Organization

## **Executive Summary**

### **Introduction**

Over the last 20 years, Ethiopia has successfully implemented its strategy of expanding and rehabilitating primary health care facilities. Parallel to the construction of health facilities, investment in human resource development and management has been scaled up; reforms to supply chain and logistics management to ensure continuous availability of health commodities at an affordable price in a sustainable manner. 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. Almost all laboratories in the system across all tiers including the National Reference Laboratories at EPHI function in facilities with sub-optimum infrastructure devoid of appropriate provisions for a safe working environment. The supply chain system has proven to be inefficient, inconsistent and unpredictable. Additionally, there are huge gaps in the implementation of Laboratory Quality Management System, 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.

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. Africa CDC investment financing program will finance the construction and equipping of BSL3 NRL which 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 a quick and effective response to public health threats.

Since BSL 3 laboratory is a place where highly infectious agents are handled and manipulated, it can have potential risks resulting in life-threatening for personnel working in BSL 3 laboratory and community. Hence, this infection Control and Waste Management Plan will ensure the protection of healthcare workers, wastes handlers, and the community as well as the environment from the harmful impacts of hazardous waste generated from the proposed BSL 3 laboratory complex and to maximize the proposed BSL 3 laboratory project compliance with international and national environmental regulations and best practices.

### **Environmental and social risks of the BSL3 NRL Complex**

Upon finalization of the construction, operating the BSL 3 laboratory complex will result in the generation of large quantity of wastes which are characterized as health care wastes (HCWs). The composition of HCWs is classified as general and infectious waste. Approximately 80% of the waste is characterised as general domestic waste and 20% is infectious such as biological waste; chemical/pharmaceutical waste and sharps materials. If a proper waste management plan is not in a position and maintained over the course of time, constructing the BSL laboratory would also solicit negative impacts to both the EPHI community and the public in general. In addition, it will overburden the existing Infection Control and Waste Management system of the facility. As the BSL 3 laboratory will generate highly infectious waste, it is important to handle, treat and dispose those wastes according to WHO recommended guidelines. Therefore, this infectious control and a waste management plan is prepared for the BSL 3 laboratory to meet a World Bank's funding requirement.

### **The Infection Control and Waste Management**

It is aligned with both international and national guidelines. To mention among others, it recognizes national healthcare waste Management guideline, and national waste management policy, World Bank safeguard policies and guidelines, WHO laboratory biosafety manual, WHO Safe health-care waste management and International Agreements and Conventions. Therefore, the document can be characterized as comprehensive ICWMP plan to implement during the operation of BSL 3 NRL complex building in managing wastes. Implementation of this ICWMP will help to prevent and/ or mitigate the negative effects of health care waste that will emanate during the operation of BSL 3 NRL complex. The management plan acknowledges the key waste management practices such as, waste minimization, proper collection segregation, storage, transportation treatment and disposal of the waste, which in turn ensures that the correct disposal procedures are taken, personnel safety is maintained, and environmental harm is minimized. Moreover, correct and efficient waste management will only be achieved through rigorous training and education of employees, supervisors and managers. As a milestone, the ICWM plan acknowledges the major mitigation measures based on the operation of BSL 3 NRL complex and they are identified as waste.

**Risk associated with waste management:** during the operational phase of the BSL 3 laboratory and other units of the complex, it is anticipated that solid and liquid wastes are generated as non-hazards and infectious/hazardous waste. Therefore, improper and inadequate waste handling, treatment and disposal can cause public health and environment risks. To avoid the risk associated with waste management, waste management strategies will be established and implemented, and all personnel working in the laboratory and waste handler would be trained on the waste handling, treatment and disposal. In addition,



new highly environment friendly pyrolytic incinerator would be purchased and installed as the existing pyrolytic incinerator getting old. Moreover, EPHI will construct new septic tank for liquid waste treatment in order to improve the capacity of the existing septic tank.

**Waste management in BSL 3 NRL Complex** Running the BSL3 laboratory generates both hazardous and non-hazardous wastes. Wastes such as highly infectious liquid and solid waste, pathological wastes, microbiological wastes, sharps, chemical and disposable wastes are categorized as hazardous wastes. While running BSL 3 laboratory, it is imperative to design a waste management strategy that enables to handle hazardous wastes aseptically, so as to safeguard the public health. Mitigation strategies stipulated to manage wastes generated from the BSL 3 NRL complex encompasses waste minimization, segregation, packaging, colour coding, collection, handling, storage, transportation, treatment, and disposal.

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

#### **Waste Storage**

BSL 3 NRL complex will designate an area within its premises where waste can be temporarily stored until the final collection for disposal and onward treatment. The waste generated from BSL-3 NRL complex would be managed as follows:

- Infectious & Pathological waste storage: the storage place will be identified as an infectious waste area by using the biohazard sign.
- Chemical waste storage: when planning storage places for hazardous chemical waste, the characteristics of the different chemicals to be stored and disposed of will be considered (flammable, corrosive, explosive).
- The storage place will be an enclosed area and separated from other waste storage areas.
- The liquid wastewater would be poured into the existing and or newly constructed septic tank

## **Transportation**

Waste transportation involves conveying of wastes from the various points of generation within a laboratory to a temporary storage location and to treatment (incinerator) and disposal facility. All waste bags/containers will be intact and covered with lids and it will be transported using carts, or containers. Infectious waste can be transported together with used sharps waste using an intact and leak-proof strong plastic bag or a container. Infectious waste will not be transported together with other hazardous and non-hazardous waste. The wastewater will be treated onsite and would be transported to Kaliti Waste Water Treatment Plant when meets the effluent quality standards.

## **Waste treatment and disposal**

**Hazardous wastes: The hazardous waste** generated during laboratory operation will be treated on site of collection or generated using the methods of autoclaving, and chemical disinfection.

**Non-Hazardous Waste:** This waste will be disposed of similarly to domestic in municipal waste collection.

**Infectious Wastes:** (Items contaminated with blood and body fluids, including cotton, pathological wastes, culture wastes, and other infectious wastes): These wastes will be autoclaved at a temperature of 121°C for at least 20 minutes at the source. After treatment, wastes would be incinerated.

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

**Sharps:** (Needles; syringes; scalpels; blades; glass, etc.) all used sharps will be placed in specific cardboard boxes called safety boxes and incinerated preferably in an appropriate double-chamber (>850°C) incinerator.

**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 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 will also consider the

assessment of the capacity of Kotebe waste treatment plant and Sendafa sanitary landfill for handling incineration residues

**Liquid waste Disposal:** after onsite treatment and laboratory confirmation was performed the treated wastewater will be connected to central wastewater treatment plants through the city's sewer line into Kality wastewater treatment plant which is under construction to be finalized within less than 2 years. If the construction of the NRL complex completed before the construction of the sewer line EPHI will use trucks to transport waste into the treatment plant. 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. 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 will also consider the assessment of the capacity of Kotebe waste treatment plant and Sendafa sanitary landfill for wastewater sludge

#### **Air pollution from incineration**

Medical waste incinerations emit toxic air pollutants and toxic ash residues that are the major source of dioxins and furans in the environment. To avoid toxic pollutant 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.

**Chemical Exposure Risk:** Occupational chemical exposure may result from laboratory procedures performing and handling of chemicals. All staff will be trained in handling and controlling of chemicals . Only amounts of chemicals necessary for daily use will be stored in the laboratory. Engineering and administrative control measures will be implemented to avoid the release of hazardous substances into the work environment. Appropriately first-aid stations with Materials Safety Data Sheets (MSDS).will be easily accessible throughout the place of work,

#### **Monitoring the implementation of the ICWMP**

It is established that the ultimate goal of the management plan is to make sure that hospital-acquired infections, injury, and illness caused by poor Infection Control and Waste Management are halted with a

system that runs efficiently with a lower cost possible. In reference to this, the management plan designed for BSL 3 laboratory complex is expected to ensure the goals are met, though the process of a stringent monitoring plan with defined indicators. As a result, the documents clearly outlined monitoring plans for each mitigation plan, which further requires both internal and external processes of monitoring and evaluation with the involvement of all concerned parties that are working at the federal and regional level. More specifically, the FMOH, and EPHI are identified as key actors during the implementation and monitoring of this ICWMP. In general, the following three generic indicators will be used as key milestones to monitor progress in implementing the medical waste management plan:

- Existence of human resource capacity in a health care facility with basic knowledge to deal with medical waste;
- Existence of records on waste generation; and
- Development of mechanisms for proper and safe healthcare waste management & disposal.

### **Capacity building**

Speaking of capacity building, the management plan will not be realized without mainstreaming a tangible capacity building plan and need-based training modules for key actors at all levels. Hence, to ensure a sustainable ICWM system, human capacity building will be substantiated through continuous education and training, with the main focus on acquainting health facility staffs and the public with basic knowledge of medical waste, fostering behavioural change amongst waste generators, mainstreaming proper handling of health care wastes and ensuring safe work practices. Moreover, thriving health care waste administrators and leaders who are qualified to lead, build and maintain the system are also identified as strategically important.

### **Cost for ICWMP Implementation**

The total budget required for the provision and implementation of the ICWMP for BSL 3 laboratory including monitoring and evaluation is estimated to be One Million Thirty Seven Thousand Five and One US Dollars (**\$1,037,001.00**).

## **1. Introduction**

### **1.1 Background**

In 2017 Ethiopia had an estimated population of 105 million and is the second-most populous country of Africa after Nigeria most populous landlocked country in the continent of Africa. In the past two decades, the Government of Ethiopia (GoE) 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 Millennium Development Goals (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. New HIV infections have dropped by 90% and mortality has been cut by more than 50% among adults. Additionally, 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.

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 311 hospitals have been constructed. Parallel to the construction of health facilities, investment in human resource development and management has been scaled up; reforms to supply chain and logistics management to ensure continuous availability of health commodities at an affordable price in a sustainable manner; and strengthening of 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 infrastructure devoid of appropriate provisions for a safe

working environment. The supply chain system has proven to be inefficient, inconsistent and unpredictable. Instrumentation with state-of-the-art technologies is in its infancy compounded with an 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. Additionally, there are 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 GoE has developed the Health Sector Transformation Plan (HSTP), which is part of the second Growth and Transformation Plan (GTP II). HSTP is 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 GoE 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, Ethiopia has 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 the Ethiopian population. The present World Bank financed Africa CDC Regional Investment Financing Program (ACRIFP) aims at achieving this. 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. As part of the ACRIFP project, BSL 3 laboratory will be constructed at EPHI premise.

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 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 a 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. Preparations for the design/construction of the proposed new BSL-3 NRL complex project are almost complete and the design will be prepared by the experience and competent company. The Government of the Republic of Ethiopia, with funding from the World Bank, plans to construct a BSL-3 NRL complex.

This Infection Control and Waste Management Plan (ICWMP) is therefore prepared for the proposed new BSL-3 National Reference Laboratory complex to be constructed in the premises of EPHI by incorporating site-specific assessments for the future activities of the project to minimize biohazard wastes, collection, treatment, and disposal of laboratory generated wastes and control infection during the operation of the BSL 3 laboratory.

Health care wastes are wastes that primarily originate from the health sector and include sharps, non-sharps, blood, body parts, chemicals, pharmaceuticals, medical devices and radioactive materials. Health care waste constitutes an important factor concerning environmental contamination, a factor of significant health risk, threatening peoples' quality of life. Thus, managing this type of waste is the main concern for governments and needs special attention by institutions and as well as by the general public. In many countries, poor handling of waste materials contaminated with infectious agents like HIV/AIDS has a severe consequence among health care workers and waste scavengers. Poor handling of HCW including those originating during operation of the project exposes health care workers, waste handlers and the community to disease and injuries. The activity of the project is expected to generate wastes and by-products that are hazardous to both human health and the environment. Also, among the general population some people (particularly children who live on the streets), usually search for reusable materials in landfills and public dumps. This activity is even graver because it leads to the manipulation and use of contaminated waste, increasing environmental and sanitary risks.

Statistics show that around the world the contamination by HIV/AIDS, through the manipulation of contaminated health care waste, represents around 0.2%. This problem represents a serious public health problem and an environmental concern within the fight against HIV/AIDS. In consequence of health care

services, significant quantities of health care waste are generated, in different categories: sharps (needles, scalpels, blades, etc.), non-sharps (blood and other body fluids, infected or not, chemicals, pharmaceutical products), and medical equipment. Because of a health care waste mismanagement, the risk of infection is higher among health care professionals, cleaning and sweeping personnel, maintenance personnel, patients and visitors, as well as within the community as a whole. The implementation of a suitable Infection Control and Waste Management Plan is an important step leading to increased quality of life, health-related cost reduction, and new recycling opportunities. A proper Infection Control and Waste Management should consider topics like policies and laws/regulations definition, human resources, allocation of financial resources and training and awareness-raising programs, for people involved in the Health Care Waste subject (health care personnel, cleaning staff, other staff etc.) and also for general population, regarding infectious diseases (like HIV/AIDS, Hepatitis B & C), other transmittable diseases like Ebola, avian flu, tuberculosis.

Since BSL 3 laboratory is a place where highly infectious agents are handled and manipulated, it may have potential risks resulting in life-threatening for personnel working in BSL 3 laboratory and community. Hence, this infection Control and Waste Management Plan will ensure the protection of healthcare workers, wastes handlers, and the community as well as the environment from the harmful impacts of hazardous waste generated from the proposed BSL 3 laboratory complex and to maximize the proposed BSL 3 laboratory project compliance with international and national environmental regulations and best practices.

## **1.2 Description of the proposed BSL-3 National Reference Laboratory Complex**

The proposed National Reference Laboratory (NRL) building complex would be designed to lie on 1,700m<sup>2</sup> area. In conformity with the city master plan, the proposed NRL building will be a 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 12,000m<sup>2</sup>, consisting of 8000m<sup>2</sup> of Laboratory spaces and 4,000m<sup>2</sup> 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.

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 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.

### **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 1,700m<sup>2</sup> 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 12,000m<sup>2</sup>, consisting of 8000m<sup>2</sup> of Laboratory spaces and 4,000m<sup>2</sup> 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.

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. LN<sub>2</sub>), and “low temperature” as temperatures between  $0\text{ }^{\circ}\text{C}$  and  $-80\text{ }^{\circ}\text{C}$  details are described in the ESIA.

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.

### **1.3 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 6 in ESIA document. Hence, the proposed BSL3 lab will be annually verified using the checklist in Annexed (annex 5) in ESIA document.

## **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.

### **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.

### **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.

## **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.

### **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.

### **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.

### **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.

### **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.

### **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.

### **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.

### **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.

### **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.

### **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.

### **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).

### **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. Infection Control and Waste Management at the proposed BSL3 National Reference Laboratory Complex**

### **2.1 Type of Medical Wastes Expected from the BSL3 NRL complex**

Healthcare/Medical waste is defined as “all waste generated by health-care establishments (human or veterinary), including research facilities and laboratories. It can include waste generated in the course of healthcare in homes. Hazardous healthcare waste is of primary concern, due to its potential to cause infections, disease or injury. Precise definitions of types of healthcare waste (HCW) must consider the associated hazards and should be incorporated into Ethiopia healthcare waste management (ICWM) legal, regulatory, technical, and information documents.

According to the WHO, about 20% of total health-care waste would be infectious waste, and improper handling of health care waste can cause serious health problem for workers, community and environment. Report showed that worldwide, about 5.2 million people (including 4 million children) die each year from waste related diseases]. The hazards of exposure to health care waste can range from gastro-enteric, respiratory, and skin infections to more deadly diseases such as HIV/AIDS, and Hepatitis (Babanyara et. al 2013). WHO reported that globally, injections with contaminated syringes caused 21 million hepatitis B infections (32% of all new infections), 2 million hepatitis C infections (40% of all new infections) and 260,000 HIV infections (5% of all new infections). More specifically medical waste has a high potential of carrying micro-organisms that can infect people who are exposed to it, as well as the community at large if it is not properly disposed of. Many of these infections were avoidable if the wastes had been disposed of safely (WHO 2004b)

Although treatment and disposal of health-care waste reduces risks, indirect health risks may occur through the release of toxic pollutants into the environment through treatment or disposal. For instance, landfills can contaminate drinking-water if they are not properly constructed. Occupational risks exist at disposal facilities that are not well designed, run, or maintained. Furthermore, incineration of waste has been widely practiced but inadequate incineration or the incineration of unsuitable materials results in the release of pollutants into the air and of ash residue. Incinerated materials containing chlorine can generate

dioxins and furans, which are human carcinogens and have been associated with a range of adverse health effects. Incineration of heavy metals or materials with high metal content (in particular lead, mercury and cadmium) can lead to the spread of toxic metals in the environment. Dioxins, furans and metals are persistent and bioaccumulate in the environment. Materials containing chlorine or metal should therefore not be incinerated.

The average distribution on types of medical waste for purposes of waste management planning is approximately 80% general domestic waste (Non-infectious) and 20% infectious such as biological/pathological waste; chemical/pharmaceutical waste and sharp materials. The quantity of these wastes generated varies greatly between the different categories and location of HCFs. Variations in the composition of waste raises serious issues at the local level which require different approaches with respect to necessary medical waste management procedures to be applied in order to achieve sustainability. The variations may be due to several factors among which are differences in HCF specialization, numbers of qualified health care personnel available, medical waste management practices prevailing as well as recycling and reuse.

The WHO Safe Management of Wastes from Healthcare Guideline and Ethiopia Healthcare Waste Management National Guideline 2008 categorizes healthcare waste into two groups as hazardous and non-hazardous wastes, and the hazardous waste is also classified into 7 classes of solid waste and 1 liquid waste.

**Table 1: WHO’s Categories of Health-Care Waste**

Waste categories	Descriptions and examples
<b>Non-hazardous or general health-care waste</b>	Waste that does not pose any specific biological, chemical, radioactive or physical hazard.
Infectious waste <i>(Including highly infectious waste)</i>	Waste known or suspected to contain pathogens and pose a risk of disease transmission, e.g. waste and waste water contaminated with blood and other body fluids, including highly infectious waste such as laboratory cultures and microbiological stocks; and waste including excreta and other materials that have been in contact with patients infected with highly infectious diseases in isolation wards.
<b>Sharps waste</b>	Used or unused sharps, e.g. hypodermic, intravenous or other needles; auto-disable syringes; syringes with attached needles; infusion sets; scalpels; pipettes; knives; blades; broken glass.
<b>Pathological waste</b>	Human tissues, organs or fluids; body parts; fetuses; unused blood products.
<b>Pharmaceutical waste,</b>	Pharmaceuticals that are expired or no longer needed; items contaminated by, or

<b>cytotoxic waste</b>	containing, pharmaceuticals.  Cytotoxic waste containing substances with genotoxic properties, e.g. waste containing cytostatic drugs (often used in cancer therapy); genotoxic chemicals.
<b>Chemical waste</b>	Waste containing chemical substances, e.g. laboratory reagents; film developer; disinfectants that are expired or no longer needed; solvents; waste with high content of heavy metals, e.g. batteries, broken thermometers and blood pressure gauges.
<b>Radioactive waste</b>	Waste containing radioactive substances, e.g. unused liquids from radiotherapy or laboratory research; contaminated glassware, packages or absorbent paper; urine and excreta from patients treated or tested with unsealed radionuclides; sealed sources.

### **Infectious waste (clinical waste)**

Infectious waste is comprised of all biomedical and health care waste known to have the potential of transmitting infectious agents to human or animals. This includes material contaminated with blood or body fluids.

### **Sharps**

Sharps are all objects and materials that pose a potential risk of injury and infection due to their puncture or cutting properties (e.g., syringes with needles, blades, broken glass). For this reason, sharps are considered one of the most hazardous categories of waste generated during medical activities.

### **Pathological and anatomical wastes**

Pathological waste groups all organs and tissues (including placentas), as well as blood and body fluids, and it is handled according to the precautionary principle stipulated by WHO.

Anatomical waste consists of recognizable body parts. It is primarily for ethical reasons that special requirements must be placed on the management of human body parts. They can be considered a subcategory of pathological waste.

### **Pharmaceutical and cytotoxic waste**

Pharmaceutical waste includes a multitude of active ingredients and types of preparations. This category of waste comprises expired pharmaceuticals or pharmaceuticals that are unusable for other reasons. Cytotoxic waste may be considered a subgroup of hazardous pharmaceutical waste, due to its high degree of toxicity. The potential health risks for people who handle cytotoxic pharmaceuticals results, above all, from the mutagenic, carcinogenic and teratogenic properties of these substances.

### **Highly infectious waste**

Highly infectious waste includes all viable biological and pathological agents artificially cultivated in significant elevated numbers. Cultures and stocks, dishes and devices used to transfer, inoculate and mix cultures of infectious agents belong to this category of waste.

### **Radioactive waste**



Radioactive waste includes liquids, gas and solids contaminated with radio nuclides whose ionizing radiations have genotoxic effects. These are found in the waste products from patients who are undergoing radiation treatment.

### **Special hazardous waste (waste with high contents of heavy metals)**

Special hazardous waste refers to chemical wastes that can pose health problems when they come in contact with people by accidental inhalation, skin contact and/or ingestion. This includes gaseous, liquid and solid chemicals, waste with a high content of heavy metals such as batteries, pressurized containers, broken thermometers, blood pressure gauges, photographic fixing and developing solutions in X-ray departments, and halogenated or non-halogenated solvents.

### **Effluents**

Effluents are a non-chemical liquid wastes that comes out of laundry, kitchen, toilet, shower and laboratory rooms which may be contaminated by pathogenic microorganisms. Effluents from isolation wards and medical diagnostic laboratories should be considered as hazardous liquid waste that should receive specific treatment before being discharged into the sewer/drainage system, if such a system exists. During operation of the BSL-3 NRL complex, 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. While the Ethiopian 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.

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 2.

**Table 2:** 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
<b>Infectious waste</b>	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.
<b>Pathological waste</b>	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.
<b>Sharps</b>	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.
<b>Liquid Waste</b>	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.
<b>Non-hazardous Waste</b>	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

### **2.2 Quantities of Waste Expected from proposed BSL 3 NRL complex and Current Practice**

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, it was tried to assess the waste generated by the mobile BSL 3 laboratory found at EPHI. The finding showed that on average 4 kg per day, (20 kg per week 8 kg per week) hazardous waste is generated. Besides on average 60 litres per day (300 liters per week) of sanitary liquid waste, 175 litres per day (3,500 lifters per week) liquid waste and since non-hazardous waste from BSL 3 laboratory is rare due to handling of highly infectious, it was estimated to be about 1 kg per day (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 3 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 an average 25 litres (125 litres per week) liquid waste and about 120 sanitary liquid waste per day (600 litres per week). The proposed BSL 3 laboratory would produce five times than the mobile BSL 3 laboratory so that the laboratory liquid waste would be 125 litres liquid waste per day (375 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 NRL complex, from the central warehouse and LEMC negligible quantities of hazardous waste is expected whereas PTPC and Biobank would 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 litres liquid waste per day (125 litres per week) and sanitary liquid waste generated from BSL 2, PTPC, Biobank, LEMC and Central ware would be about 360 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 litres 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 NRL complex (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 sufficient for daily activities. 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 litres 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 or too acidic to meet discharge standards.

### **2.3 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.

### **2.4 Environmental and social risks associated with the BSL3 NRL and Mitigation**

#### **Strategies**

In the BSL 3 laboratory there would be highly infectious agents in storage, diagnosis process or culture and in waste generated from the BSL 3 NRL complex. So, that there would be a possibility to escape infectious agents BSL-3 if waste management system is weak. Potential means for infectious agents to leave with untreated waste 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. So that the BSL 3 NRL complex would apply the best practices for waste management recommended by WHO, and CDC. The best practice of waste management system in the proposed BSL 3 NRL is prepared based on the WHO Safe management of wastes from healthcare guideline, Ethiopian Healthcare waste Management guideline and WBG EHS and OSHA guidelines.

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 NRL complex 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.

#### **2.4.1 Risks due to improper Healthcare 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%). Sharps waste, although produced in small quantities, is highly infectious. If poorly managed, healthcare workers, waste handlers and the community can be exposed to infections. Contaminated needles and syringes 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 be infected with HBV, HCV and HIV.

The assessment conducted by WHO, 2002 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 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 that health professionals are also exposed to infectious waste and sharps during healthcare delivery and also exposed to such risks during waste collection, storage, transport, treatment and disposal. Furthermore, risks as a consequence 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 such as incineration, involves health risks to the operators. (Bokhoree et al. 2014). Mostly 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. Risks associated with waste management and impacts with mitigation measures are summarized below.

The potential for illnesses and injuries involving routine laboratory operations presents a greater health risk to workers than does handling infectious substances as the proposed BSL 3 laboratory would handle highly infectious agent list annexed (Annex 11). 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.

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 BSL 3 laboratories. Doubtlessly, 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 1974. 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 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-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 n 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 in advance of the constrictions.

#### **2.4.2 Risks during Management of Medical Wastes**

Although treatment and disposal of health-care waste reduces risks, indirect health risks may occur through the release of toxic pollutants into the environment through treatment or disposal. For instance, landfills can contaminate drinking-water if they are not properly constructed. Occupational risks exist at disposal facilities that are not well designed, run, or maintained. Furthermore, incineration of waste has

been widely practiced but inadequate incineration or the incineration of unsuitable materials results in the release of pollutants into the air and of ash residue. Incinerated materials containing chlorine can generate dioxins and furans, which are human carcinogens and have been associated with a range of adverse health effects. Incineration of heavy metals or materials with high metal content (in particular lead, mercury and cadmium) can lead to the spread of toxic metals in the environment. Dioxins, furans and metals are persistent and bioaccumulate in the environment. Materials containing chlorine or metal should therefore not be incinerated.

A study conducted by Derso et al in 2018 on Ethiopian health facilities showed that safe medical waste disposal method was high in referral hospitals (87.9%). Similar study conducted in Addis Ababa on 2014 by Tadesse et al, revealed that the average healthcare waste generation rate was 9.6 kg/d, of which 62% (5.97 kg/d) was hazardous. The proportion of health facilities using safe medical waste disposal methods was higher in urban areas (74.5%) compared with health facilities in rural areas (61.1%). In addition, the proportion of health facilities using safe medical waste disposal methods was high among those who had guidelines for waste management in the service area (82.7%) compared with those who did not (73.5%) (Derso et al 2018).

Although EPHI has waste disposal facilities, due to additional waste expected from the proposed facility, new septic tank would be developed as a result of the proposed action and the waste liquid waste plan described in chapter 6, section 16.5 and the design also depicted in figure 8. Septic tanks would be used to capture biological liquid waste to ensure disinfection is adequate prior to discharge to the sanitary sewer system by vehicle. There would be no need for waste accumulation areas since no hazardous waste would be produced (hazardous chemicals would be used up in process or leave the building as a stabilizing product for microorganisms and biological material).

During the operational phase of the BSL 3 laboratory it is anticipated that solid and liquid wastes are generated on a daily basis. Most of the BSL-3 wastes generated would be considered as highly infectious but there would be small amount of nonhazardous waste. Since laboratory activities involve certain medical examinations and also there will be a need for usage of different sorts of chemicals or reagents, it can be predicted that different types of hazardous wastes 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 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 and treatment. These constitute a grave risk, if they are not properly handled, treated or disposed and otherwise are allowed to get mixed with other municipal waste. 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 medium. Sensitivity of receptors due to improper medical waste management is medium, thereby giving major impact significance.

### **2.4.3 Mitigation strategies for Management of Risks associated with improper management of waste**

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 and procedures waste management described in this chapter.

- Develop and implement a waste management plan for EPHI in general and for the proposed NRL project in particular in accordance with the national Infection Control and Waste Management Plan to guide the daily waste management operations.
- 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.
- EPHI has two functional incinerators to dispose medical wastes through burning and there is a proposed one for purchase which has high efficiency.
- All Sharps used in the BSL-3 would be autoclaved prior to incineration.
- Solid waste generated in the BSL-3 laboratory would leave the laboratories only after decontamination using the laboratory's autoclave.
- Non-hazardous waste 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 (color 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.

#### **2.4.4 Risks associated with incineration of waste**

In recent years, incineration and combustion of solid waste have 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 Nm<sup>3</sup>. Therefore, it is important to treat the flue gas to reduce its concentration to an acceptable limit (0.1 ng TEQ Nm<sup>3</sup>) before releasing it to the environment (Kulkarni et al., 2008). In that context, ambient air monitoring is an essential issue to estimate pollutant emissions such as dioxins.

Thus, the waste generated from proposed BSL 3 laboratory do have negligible amount of polychlorinated dibenzo-para-dioxins materials that a result of the combustion of chlorine-containing wastes precursor for formation of dioxins, and heavy metals wastes that have risk for the staff, community, and environment and the amount of wastes generated BSL 3 lab from is also a small amount of wastes. During the operation BSL 3 laboratory, wastes are generated, and they would be treated using different techniques such as autoclave, chemical disinfectant, incinerators. However, the incinerator would contribute to air pollution. So that air quality effects during the operation of the incinerator generate emissions of SO<sub>2</sub>, CO<sub>2</sub>, CO, NO<sub>x</sub>, particulates and other toxic substances. Incineration presents a good option for good disposal and destruction of solid and sharps-wastes. However, concerns such as availability of technical know-how, 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 a good emissions management system.

#### **2.4.5 Mitigation strategies for Impact due to incineration of waste**

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

- Workers will be provided with PPE and the use of PPE would be enforced.
- Improve incinerators and infrastructure for healthcare waste treatment and disposal
- Maintain the existing incinerators periodically
- Purchase new environmentally friendly incinerator.
- Monitor the emission coming out from incinerators

#### **2.4.6 Chemical Hazards**

Handling chemicals is a typical part of the day-to-day routine 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 research institute as well as a reference laboratory, EPHI use a large amount of chemical for different purposes. Professionals have 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.

#### **2.4.7 Mitigation measures for risks associated with hazardous chemicals**

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 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

## **2.5 Waste management approaches and standards for the BSL 3 NRL Complex**

During operation of this BSL3 NRL complex 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 color. 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 EHPI campus need to fulfil the emission standard on WBG EHS guidelines (2007) see annex 9 the specification for the incinerator.

**Table 3: Air Emission Levels for Hospital Waste Incineration Facilities**

Pollutants	Units	Guidance value
Total Particulate Matter (PM)	mg/Nm <sup>3</sup>	10
Total organic carbon (TOC)	mg/Nm <sup>3</sup>	10
Hydrogen chloride (HCl)	mg/Nm <sup>3</sup>	10
Hydrogen fluoride (HF)	mg/Nm <sup>3</sup>	1
Sulfur dioxide (SO <sub>2</sub> )	mg/Nm <sup>3</sup>	50
Carbon monoxide (CO)	mg/Nm <sup>3</sup>	50
NO <sub>x</sub>	mg/Nm <sup>3</sup>	200-400 (a)
Mercury (Hg)	mg/Nm <sup>3</sup>	0.05
Cadmium + Thallium (Cd + Tl)	mg/Nm <sup>3</sup>	0.05
Sb, As, Pb, Cr, Co, Cu, Mn, Ni and V	mg/Nm <sup>3</sup>	0.5
Polychlorinated dibenzodioxin and dibenzofuran (PCDD/F)	Ng/Nm <sup>3</sup> TEQ	0.1
Notes:		
a. 200 mg/m <sup>3</sup> for new plants or for existing incinerators with a normal capacity exceeding 6 tones per hour, 400 mg/m <sup>3</sup> for existing incinerators with a nominal capacity of 6 tones per hour or less		
b. Oxygen level for incinerators is 7 percent		

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.

### 2.5.1 Waste management within BSL 3 NRL Complex

All biological wastes from BSL-3 NRL complex 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.

### **2.5.2 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 NRL complex 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.

### **2.5.3 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 Infection Control and Waste Management National Guidelines. In essence, waste segregation and waste color coding work hand in hand. The waste generated from BSL 3 laboratory, described above, will be segregated and color-coded as outlined below in table 3 as recommended by WHO.

**Table 4: BSL 3 NRL complex waste collection and segregation methods**

Waste categories	Colour of container and markings	Type of container	Collection frequency
<b>Infectious waste</b>	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.
<b>Sharps waste</b>	Yellow, marked <i>SHARPS</i> with biohazard symbol.	Puncture-proof container.	When filled to the line or three-quarters filled.
<b>Pathological waste</b>	Yellow with biohazard symbol.	Leak-proof strong plastic bag placed in a container.	When three-quarters filled or at least once a day.
<b>Chemical waste</b>	Brown, labelled with appropriate hazard symbol.	Plastic bag or rigid container.	On demand.
<b>Non- hazardous Waste</b>	Black	Plastic bag inside a container or container which is disinfected after use.	When three-quarters filled or at least once a day.

#### 2.5.4 Colour Coding

Colour coding is done by using colours to differentiate waste classes from one other. It is efficient and helps in the process of waste segregation at source. It is also simple, easy to use and thus can be understood even by illiterate patients particularly at health posts where illiteracy level is high. Colour coding is one of the efficient ways of achieving segregation of waste and for sorting out items such as paper, plastic, glass and metal for recycling. It is important that all HCF in Ethiopia use the same colour coding scheme as this helps to minimize and avoid a waste class from mixing with other waste classes. This is also advocated in the Ethiopia National Healthcare Wastes Management Guidelines document. The recommended colour codes for health facilities are shown in Table 4. 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 5:** Three-bin system used at all health faculties in Ethiopia

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

### 2.5.5 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.

### 2.5.6 Labelling

An important aspect of color 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. In general, labelling is important in order to

- Identify the source of HCW or date of generation in case of an accident or improper segregation of the waste, ensure that the workers responsible for HCW management handle the different types

of wastes safely, ensure that each staff member feels more responsible for what they put into the bag/receptacle

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

### **2.5.7 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 color 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 off.
- 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.

### 2.5.8 Handling

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.

### **2.5.9 Waste Handling Safety Measures**

- a. 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;
- b. Protective medical clothing and PPE would not be submitted for laundering unless sterilized;
- c. 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).

### **2.5.10 Waste Storage**

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 in order 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 will be isolated at EPHI compound where larger containers found near to incinerators will be used to store waste until it is incinerated.

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

#### **2.5.11 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, the waste generated from BSL 3 NRL complex is treated and disposed both at EPHI facility (onsite) and also there will be off-site transport. So that On-site transport involves conveying of wastes from the various points of generation within a laboratory to a temporary storage location also within the same area



### **Onsite transportation.**

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

- Every effort would be made to avoid unnecessary handling of HCW;
- All waste bags would in-place and intact at the end of transportation;
- Carts, 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.

### **Offsite 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.

#### **2.5.12 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 ICWM 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 6 below.

**Table 6: 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 in the laboratories	BSL 3 NRL, BSL 2 Labs, PPTC & Biobank centre,	280 litres/day	All effluents in HCFs will be disinfected with bleach and drained to a septic tank or cesspool for both storage and treatment in the compound of EPHI.
		BSL 3 NRL, BSL 2 Labs, PPTC, Biobank centre, Central ware house & LEMC	720 litres/day	
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.

### **2.5.13 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 upto <0.1 ng TEQ/m<sup>3</sup>. 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 company which can handle demolition of the existing incinerators before the BSL3 NRL complex 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. The 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.

### **2.5.14 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 will also consider the assessment of the capacity of Kotebe waste treatment plant and Sendafa sanitary landfill for handling incineration residues.

The Kality had capacity of 7,600 m<sup>3</sup>/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 m<sup>3</sup>/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, with an estimated volume of 85,000 m<sup>3</sup>/day. 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.

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 m<sup>3</sup>/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 m<sup>3</sup>/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 plan. The Kotebe treatment plant is established in the territory norther part of the city far away from residential and business centre and there are 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.

#### **2.5.15 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, liquid waste treatment plan design described below and shown in figure 7. Liquid wastes with highly infectious would be treated using 5% sodium hypochlorite ( $\text{NaOCl}$  – 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 2 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.

### **2.5.16 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 with 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 laboratories 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 with in 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.

### **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.

### **2.5.17 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.

#### **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 hydrolyzing 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.

#### **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 centimeters) 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 are able to thrive deeper in this active surface layer, where nitrification will readily occur.

### **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 are capable of providing significant ammonia oxidation and effective removal of organic matter. The basic system consists of a number of interrelated components (as shown in figure 1 **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 sufficient 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.

### **Disinfection: Ultraviolet irradiation**

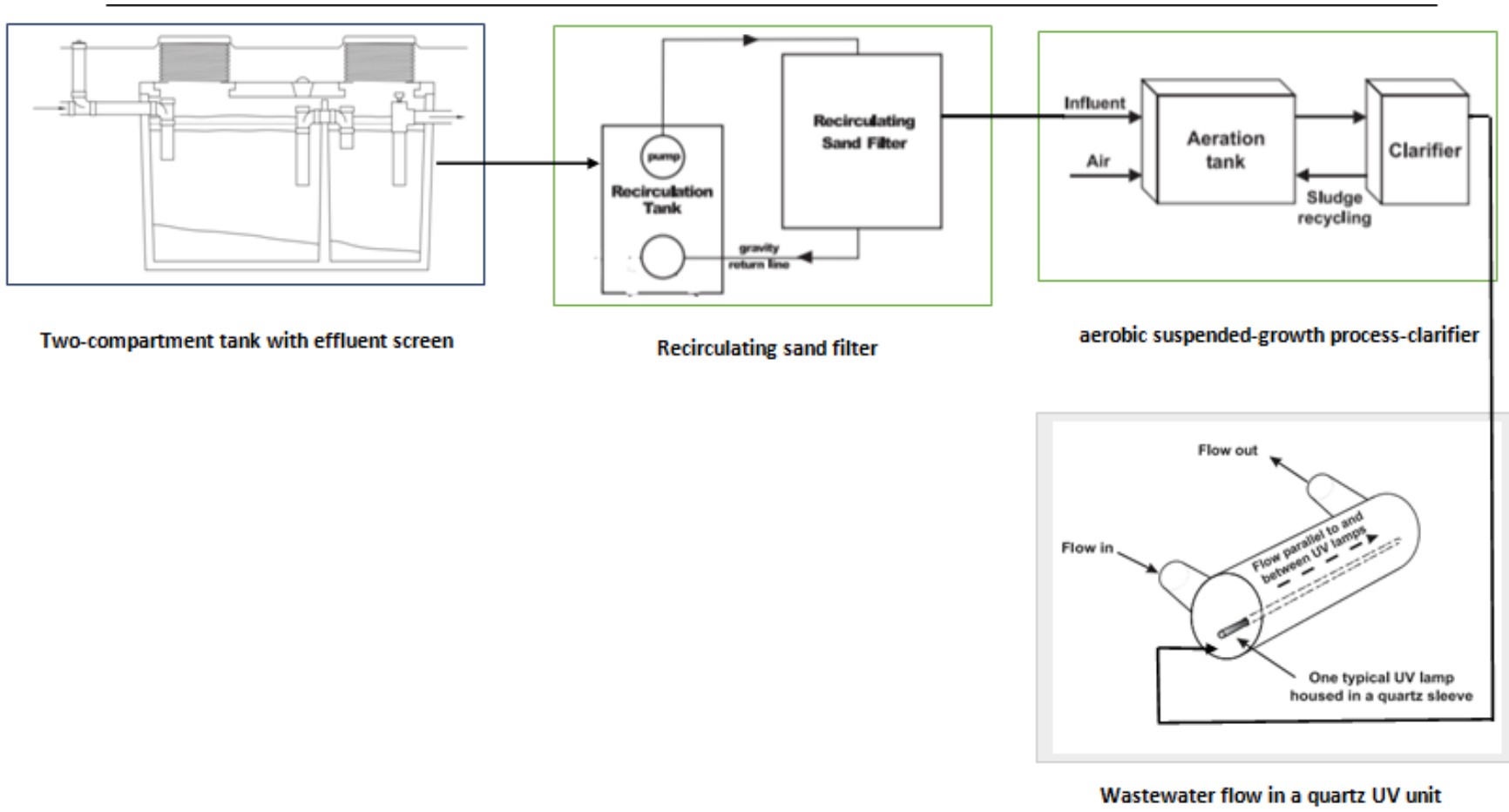
The germicidal properties of ultraviolet (UV) irradiation have been recognized for many years. UV is germicidal in the wavelength range of 250 to 270 nm. The radiation penetrates the cell wall of the organism and is absorbed by cellular materials, which either prevents replication or causes the death 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 7:** Expected performance of the BSL3 NRL complex liquid waste treatment units

Treatment units	Performance	Performance enhancements
Septic tank	The main function of a septic tank is to act as a primary settlement tank removing some of the BOD and the majority of the suspended solids from the waste water	Chemicals such as aluminum sulphate and ferric chloride can be used to enhance settlement in these tanks.  Aluminum sulphate are 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 aluminum sulphate will depend on the periodic testing of effluent released from the BSL3.
Sand/media filters	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.  Removal of carbonaceous BOD and ammonium-nitrogen  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.  Sand filter effluents have provided more than 3 logs of FC removal and more than 4 logs of poliovirus removal. Since this level of pretreatment 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 with several large-scale water reuse studies that show that filtered effluent can reach essentially FC-free levels (<1CFU/100mL)	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
Continuous-flow, suspended growth	Converts soluble and colloidal biodegradable organic matter and some inorganic compounds into cell mass and metabolic end products	The use of coarse membrane filters in lieu of, or in addition to, the clarifier; and process enhancement through the addition of

aerobic systems	<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. Fecal coliform and virus removal have been reported in the range of 1 to 2 logs.</p>	<p>an inert media area on which biofilms can grow. 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/cm<sup>2</sup>, while higher (but attainable) effluent FC levels require less dosage to filtered effluent (about 48 mW-s/cm<sup>2</sup>) than is required by aerobic unit effluent (about 60 mW-s/cm<sup>2</sup>). 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 1:** a schematic diagram of the liquid waste treatment facility of BSL3 NRL

### **2.5.18 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/m<sup>3</sup> 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 kaloty 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 will also consider the assessment of the capacity of Kotebe waste treatment plant and Sendafa sanitary landfill for handling incineration residues.

### **2.5.19 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) Kaloty 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. 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.

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 will also consider the assessment of the capacity of Kotebe waste treatment plant and Sendafa sanitary landfill for wastewater sludge.

### 2.5.20 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 7) 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 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.

**Table 8: 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 <sup>a</sup>	400
Polychlorinated dibenzodioxin and dibenzofuran (PCDD/F)	Ng/L	0.1
Temperature increase	°C	<3 <sup>b</sup>



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.

## **2.5.21 BSL 3 NRL Complex Sample Handling and Transportation**

### **2.5.21.1 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.

#### **2.5.21.2 Transport of 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 milliliter of specimen. Smaller samples could be shipped that would be microliters in size; the maximum probable sample size would be 15 milliliters. 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

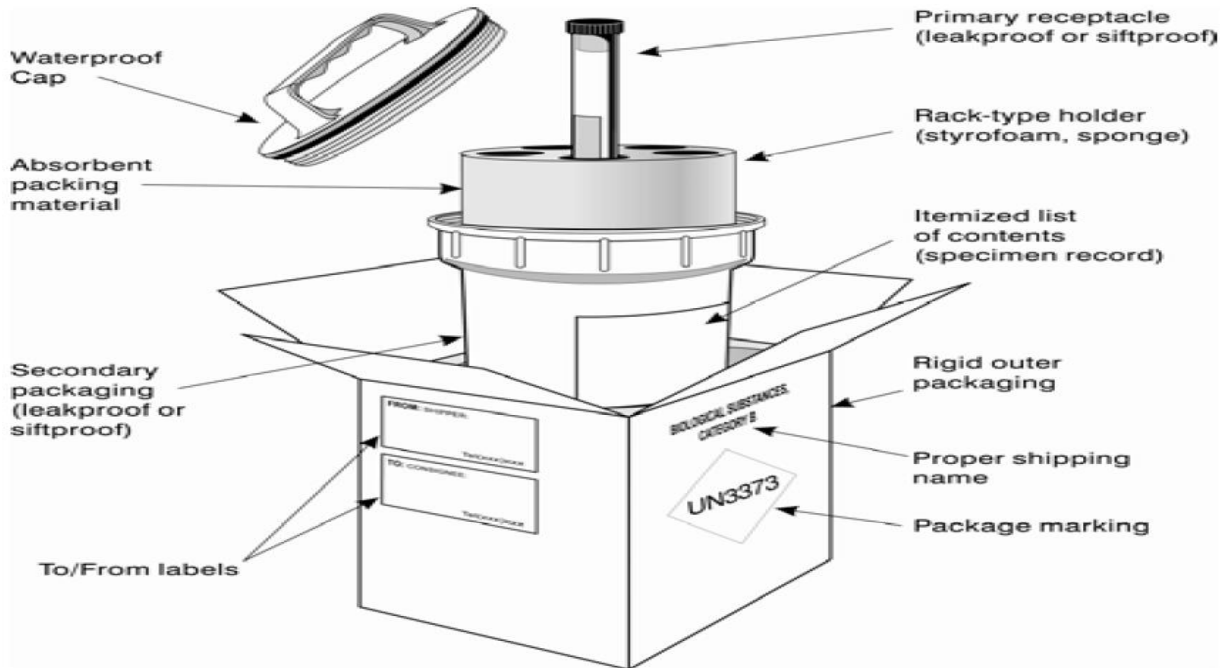
In our context due to lack of strong laboratory networking with different levels of Laboratories and regulated sample transport system we use the National postal service for transport of some biological samples from far localities and .therefore it demands to pack specimen containers in triple packing 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](http://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 be 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 2: 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).

## 2.6 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 affect 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 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.

Therefore, the BSL 3 NRL 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.

## **2.7 EPHI BSL 3 laboratory Staffing and Capacity Building**

### **2.7.1.1 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 bases, 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 Operator
- Wastewater treatment Plant Operator,

### **2.7.1.2 Roles and Responsibilities**

The EHPI 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:

#### **2.7.1.3 Ethiopian Public Health Institute (EPHI)**

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.
- 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

#### **2.7.1.4 EPHI BSL3 Lab Biosafety and Biosecurity Committee**

The Biosafety Committee will oversee the review, approval and oversight of biohazards in research activities at the BSL3 lab. 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 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.

#### **2.7.1.5 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.
- 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 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.

#### **2.7.1.6 Laboratory Scientists**

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

#### **2.7.1.7 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.

#### **2.7.1.8 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.
- 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 including infection control.

- 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 of the 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.

#### **2.7.1.9 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

#### **2.7.1.10 Wastewater treatment Plant Operator**

- Effluent sampling and management of data associated with BSL 3 NRL wastewater treatment facility
- Follow infection control and 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

#### **2.7.1.11 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.

#### **2.7.1.12 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 or animal handling room.

### **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

#### **2.7.1.13 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.

#### **2.7.1.14 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

### **3. Infection Control and Waste Management Plan (ICWMP)**

#### **3.1 Plan for mitigation of risks associated with the proposed BSL3 NRL complex**

The ICWMP for the BSL 3 NRL complex will operate within the confines of the Infection Control and Waste Management Plan and seek ways and means that it will operationalize the action plan. The Infection Control and Waste Management Plan (NICWMP) identifies the indicators to be tracked, specific tasks to be executed and assigns responsibility for waste collection to specific agencies. For the plan to be effectively implemented, EPHI would develop standardized plans based on its existing needs and proposed BSL 3 NRL complex. The plan should design a mitigation strategy for potential risk associated with healthcare waste collection, handling, storage transportation treatment, and disposal. The mitigation plan includes the following but not limited:

- improper health care waste collection, storage and segregation that have a potential risk to lab professionals/ health workers, society and environment,
- Risks of disease transmission from poor waste treatment & disposal systems,
- Air pollution due to utilization of poor quality of incinerator technology
- Environmental pollution due to poor ICWM practices
- Risk of disease transmission to waste scavengers
- Shortage of equipment and supplies ICWM and PPE
- Poor management systems for infection and emergency

#### **3.2 Responsibility for the implementation of ICWMP**

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

Detail institutional arrangement, roles and responsibilities for ESMP implementation are summarized in ESIA document in Chapter 8.

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, 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.



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, and 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.

### **3.3 Mitigation Measures Plan**

The mitigation measures for anticipated risks from the proposed BSL3 lab complex is outlined in Table 10 below.

**Table 9: Infection Control and Waste Management Plan with Cost**

S.N	Potential or Major Impacts/issues	Mitigation strategies	Activities	Responsible body	Budges \$ (Proposed)
1.	Improper health care waste management have a potential risks to lab professionals/ health workers, society and environment	Ensure an efficient and effective health-care waste collection, storage and segregation system	Ensure proper waste management practices as recommended by the WBG EHS, WHO Safe waste management guidelines for improvement waste management.	FMoH/EPHI	500
			The collection of waste would be made at least once in 24 hours, and it should be done in such a way to minimize nuisance of smell and dust during collection and all the waste collected must be carried away from the storage site to an approved disposal point.	FMoH/EPHI	1,500
			Provide appropriate waste bins for the different types of waste generated in the laboratory to allow segregation and collection at the point of generation.	FMoH/EPHI	3,000
		Ensure an efficient and effective health-care waste treatment and disposal system ,	Establish waste management committee Develop waste management plan	FMoH/EPHI/	250
			Laboratory staff would be trained on waste management and handling during operation.	FMoH/EPHI	1,000
			Improve waste treatment & disposal systems like septic tank at health facility through construction of Liquid waste treatment plant	FMoH/EPHI/	95,000* Cost indicated at ESMP
			Improve waste treatment & disposal systems like septic tank at health facility through periodic maintenance	FMoH/EPHI/	45,000
			EPHI administration will work together with the Municipal Council to facilitate waste handling and disposal from the site noting that hazardous waste must not be mixed with municipal waste.	FMoH/EPHI/	500
			Laboratory would have standard operation and decontamination procedure manuals and clearly displayed at appropriate point (s) with the laboratory.	FMoH/EPHI	1, 000
2.	Shortage of equipment and supplies ICWM and PPE	provision of all necessarily equipment and supplies ICWM and PPEs	Supply all equipment and supplies required to ICWM and PPEs for HCFs (coveralls, goggles, nose guards, gloves, face masks, fixtures etc.)	FMoH/EPHI	5, 000

S.N	Potential or Major Impacts/issues	Mitigation strategies	Activities	Responsible body	Budget \$ (Proposed)
3.	Poor ICWM practices can cause air pollution, and natural resource contamination	Standardize and implement ICWM practices and avail commodities and equipment for ICWM	Develop specifications and standards for ICWM practices and equipment and supplies and disseminate for users	FMoH/EPHI	1,000
			Ensure the practice and utilization of equipment and supplies required for ICWM	FMoH/EPHI/	500
			Provide training for health workers and HCW handlers in ICWM	FMoH/EPHI	2,000
4.	Utilization of poor quality of incinerator technology can lead air pollution	Improve incinerators and infrastructure for healthcare waste treatment and disposal	Training of Incinerator Operators. Regular servicing of Incinerators. Post installation maintenance. Monitoring of the performance of Incinerators	FMoH/EPHI	3,000
			New pyrolytic incinerator will be purchased	FMoH/EPHI	50,000* for management only
5.	Lack or poor of capacity building on ICWM	Establish training/capacity building strategies and programs for all health care workers on ICWM	Develop and Review the standard ICWM training curriculum for in-service, and refresher training for all HCWs in line with emerging issues	FMoH/EPHI	1,000
			Partner with all professional and regulatory bodies to improve ICWM practices	FMoH/EPHI	500
			Provide training for health workers and HCW handlers in ICWM	FMoH/EPHI/	1,000
			Enforce Strengthen formation of PPPs of ICWM at national levels	FMoH/EPHI/	500
6.	Poor management systems for emergency preparedness	Improving health and safety of health care workers	Train staff on emergency preparedness and response	FMoH/EPHI	1,000
			Establishment of medical surveillance systems according to Ethiopian regulation	FMoH/EPHI	1,500
7.	Occupational Health and Safety risks	All workers to be provided with appropriate PPE against exposure to hazards,  Training for all staff would be given on safe work practices and guidelines and ensure that they adhere to it.	Provide appropriate PPE <sup>1</sup> against exposure to infectious pathogens, hazardous chemicals and ionizing radiation in accordance with recognized international safety standards and guidelines.	FMoH/EPHI	8,750
			Orientation for all staff would be given on safe work practices and guidelines and ensure that they adhere to it.	FMoH/EPHI	250
			Provide relevant vaccination for all health workers and supportive staffs	FMoH/EPHI	5,000

<sup>1</sup> The type PPE to be procured and associated costs are annexed.

S.N	Potential or Major Impacts/issues	Mitigation strategies	Activities	Responsible body	Budget \$ (Proposed)
		Utilizing CDC, WHO & NIH guidelines, standards, practice and procedures.	Training should 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.	FMoH/EPHI	1,000
			Regular drills should 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.	FMoH/EPHI	500
8.	Lack of M&E systems for ICWM	Establish M&E system for ICWM	Develop and disseminate M&E plan & tools for ICWM	FMoH/EPHI	500
			utilize M&E tools (tracking tools, facility audit, IPC checklist)	FMoH/EPHI	1,000
			Training, orientation and health workers induction on M&E tools and reporting	FMoH/EPHI	1,000
9.	Risk associated with the existing incinerators	Maintain the incinerators periodically	Perform preventive maintenance for the incinerators periodically	EPHI	1,500
10.	Risks associated with existing incinerator demolishing (The ESIA will be updated to cover risks associated with the demolition/decommissioning)		5,000		
10.1	Release of residue ash	Minimize Release of residue ash	The decommissioning and demolition work will be carried out in full containment, a manufacture or Specialist Contractor will be employed with adequate health and safety protection measures in place	EPHI/specialist contractor	Cost indicated within 5,000
			A suitably licensed waste collector will be used to collect, transport and dispose the chemical wastes to the designated treatment facility	EPHI/specialist contractor	Cost indicated within 5,000
10.2	Dust	Control dust release	Wet wiping of the surface to minimize airborne dust.	EPHI/specialist contractor	Cost indicated within 5,000

S.N	Potential or Major Impacts/issues	Mitigation strategies	Activities	Responsible body	Budget \$ (Proposed)
			The decommissioning and demolition work will be carried out in full containment	EPHI/specialist contractor	Cost indicated within 5,000
10.3	Release of asbestos containing materials and chemical waste	Control release of asbestos containing materials and chemical waste	The decommissioning and demolition work will be carried out in full containment, a manufacturer or Specialist Contractor will be employed with adequate health and safety protection measures in place.	EPHI/specialist contractor	Cost indicated within 5,000
			Appropriate waste collection procedure will be used to collect, transport and dispose the chemical wastes to the designated treatment facility.	EPHI/specialist contractor	Cost indicated within 5,000
10.4	Wastewater	Control Wastewater release	The floor drain in the incinerator room will be covered with a temporary seal during the decommissioning and demolition works.	EPHI/specialist contractor	Cost indicated within 5,000
			The top of the chimney would be sealed with polyethylene sheets at least twenty-four (24) hours before the works commence	EPHI/specialist contractor	Cost indicated within 5,000
11.	Impact of air pollution due to waste incineration	Purchase new environmental friendly incinerator	A new environment friendly Pyrolytic incinerator purchased & installed	EPHI/MOH	750,000 Cost indicated at ESMP
			Signed agreement between supplier and EPHI for training, maintenance and supplying spare parts	EPHI/MOH	Part of the purchasing cost
<b>Total</b>				<b>987,751.00</b>	

**\*Note:** the cost for purchasing new incinerator and septic tank construction are included in the ESIA document (845,000.00 USD)

### **3.4 Monitoring Plan for the ICWMP Implementation**

The environmental monitoring plan, summarized in table 10, for the ICWMP of the proposed BSL 3 NRL facility presents the impacts and mitigation measures associated with waste management 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 ICWMP are detailed in sections below.

Monitoring is required to follow-up on decisions made to intervene in various activities of medical waste management to minimize risks to people, animals, and the environment for protecting human health and the environment. To ensure that objectives of the ICWMP are achieved, the implementation of the plan should be monitored on a regular basis internally by EPHI and external bodies including the Federal Ministry of Health (FMOF). These institutions will determine their respective monitoring tools and will work jointly within the monitoring and evaluation mechanism of the proposed project.

#### **3.5.1 Institutional Arrangement for Monitoring Plan Implementation**

Monitoring will verify if predicted impacts have actually occurred and check that mitigation actions recommended in the ICWMP 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. 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).

#### **3.5.2 Frequency for monitoring**

Monitoring Frequency for the project is described on ESIA and ESMP. The monitoring frequency for ICWMP will be undertaken monthly during the operation phase. Audits will be necessary both during construction and project operation. During the operation phase, audits will be conducted annually and the audits can be conducted internally by EPHI or by external auditor.

### **3.5.3 Reporting System**

Monthly monitoring reports of ICWP would be compiled by Biosafety and Biosecurity Committee/ Biosafety and Biosecurity officer and PHID FMOH's Project Coordination Team and shared with FMOH and EPHI or another interested stakeholder. Operation phase auditing should including incinerator and liquid waste treatment plant unit performance and the EPHI/ MOH would share with other interested stakeholders.

**Table 10: Infection Control and Waste Management Monitoring Plan**

S.N	Mitigation strategies	Activities	Desired outcome	Monitoring: performance indicators/ target of acceptance criteria	Time frame	Responsible body	Budges \$ (Proposed)
1)	Ensure an efficient and effective health-care waste collection, storage and segregation system	Ensure proper waste management practices as recommended by the WBG EHS, WHO Safe waste management guidelines for improvement waste management.	Establish waste management system Create	Approve the implementation of WBG EHS, WHO Safe waste management guidelines	Quarterly	FMoH/EPHI	200
		The collection of waste would be made at least once in 24 hours, and it would be done in such a way to minimize nuisance of smell and dust during collection and all the waste collected must be carried away from the storage site to an approved disposal point.	Conducive environment and healthy workforce	Daily waste disposal records	Quarterly	FMoH/EPHI	200
		Provide appropriate waste bins for the different types of waste generated in the laboratory to allow segregation and collection at the point of generation.	Proper waste segregation	Presence of colour coded waste bin for all waste type	Quarterly	FMoH/EPHI	200
	Ensure an efficient and effective health-care waste treatment and disposal system ,	Establish waste management committee And develop waste management plan	Properly managing HCW  Conducive environmental system and healthy workforce	Presence of waste management committee and plan	Quarterly	FMoH/EPHI	100
		Laboratory staff would be trained on waste management and handling during operation.	Well aware staff on ICWM Proper implementation ICWM	Number of staff trained on ICWM	Annually	FMoH/EPHI	100
		Improve waste treatment & disposal systems like septic tank at EPHI through construction of additional septic tank.	Prevention of environmental pollution and protection of community health	Number of model/new technologies or septic tank established for waste disposal and treatment	Quarterly	FMoH/EPHI	100
		EPHI administration would work together with the Municipal Council to facilitate waste handling and disposal from the site	Prevention of environmental pollution	Availability of Coordination between EPHI &	Quarterly	EPHI/AAEPA	100



S.N	Mitigation strategies	Activities	Desired outcome	Monitoring: performance indicators/ target of acceptance criteria	Time frame	Responsible body	Budges \$ (Proposed)
		noting that hazardous waste must not be mixed with municipal waste.		local municipality for ICWM			
		Laboratory would have standard operation and decontamination procedure manuals and clearly displayed at appropriate point (s) with the laboratory.	Strict adherence to standard and manuals	Presence of SOP and manual for ICWM	Annually	FMoH/EPHI	150
2)	provision of all necessarily equipment and supplies ICWM and PPEs	Supply all equipment and supplies required to ICWM and PPEs for HCFs (coveralls, goggles, nose guards, gloves, face masks, fixtures etc.)	To reduce infection and injury	Avail all necessarily equipment and supplies	Quarterly	FMoH/EPHI	200
3)	Standardize and implement ICWM practices and avail commodities and equipment for ICWM	Develop specifications and standards for ICWM practices and equipment and supplies and disseminate for users	Adherence to proper equipments use and practice	Develop standard and SOP for ICWM equipment and supplies	Annually	FMoH/EPHI	150
		Ensure the practice and utilization of equipment and supplies required for ICWM	To reduce infection and injury	Presence of audit record	Annually	FMoH/EPHI	200
		Provide training for health workers and HCW handlers in ICWM	Well knowledgeable staffs on ICWM	Number of staff trained on ICWM	Annually	FMoH/EPHI	100
4)	Improve incinerators and infrastructure for healthcare waste treatment and disposal	Training of Incinerator Operators. Regular servicing of Incinerators. Post installation maintenance. Monitoring of the performance of Incinerators	Well knowledgeable staffs on proper operation of incinerators  Preventive and curative maintenance of the incinerator	Number of incinerator operator trained on ICWM and incinerator maintenance	Annually	FMoH/EPHI	300
		New pyrolytic incinerator will be purchased	Prevention of environmental pollution and protection of community health	Efficient incinerators installed for waste treatment and disposal	Annually	FMoH/EPHI	100
5)	Establish training/capacity building strategies and programs for all health care workers on ICWM	Develop and Review the standard ICWM training curriculum for in-service, and refresher training for all HCWs in line with emerging issues	Well knowledgeable staffs on ICWM	Presence of approved training materials	Annually	FMoH/EPHI	100
		Partner with all professional and regulatory bodies to improve ICWM practices	Strong partnership on ICWM	Number of cooperating partners	Annually	FMoH/EPHI	150
		Provide training for health workers and HCW handlers in ICWM	Well knowledgeable staffs on ICWM	Number of staff trained on ICWM	Annually	FMoH/EPHI/	100

S.N	Mitigation strategies	Activities	Desired outcome	Monitoring: performance indicators/ target of acceptance criteria	Time frame	Responsible body	Budget \$ (Proposed)
		Enforce Strengthen formation of PPPs of ICWM at national level	Strong partnership on ICWM	Number of cooperating partners.	Annually	FMoH/EPHI/	100
6)	Improving health and safety of health care workers	Train staff on emergency preparedness and response	Well knowledgeable staffs on emergency preparedness and response	Number of staff trained on emergency preparedness and response	Annually	FMoH/EPHI	100
		Establishment of medical surveillance systems according to Ethiopian regulation	Ensures medical service for all staff	Presence of medical surveillance system	Bi-annually	FMoH/EPHI	150
7)	All workers to be provided with appropriate PPE against exposure to hazards,	Provide appropriate PPE against exposure to infectious pathogens, hazardous chemicals in accordance with recognized international safety standards and guidelines.	Prevention of infection and injury Develop healthy work force	Number of staff provided with standardized PPE	Quarterly	FMoH/EPHI	200
	Training for all staff would be given on safe work practices and guidelines and ensure that they adhere to it.	Orientation for all staff would be given on safe work practices and guidelines and ensure that they adhere to it.	Well knowledgeable d staffs on ICWM	Number of staff oriented on safe work practices and guidelines	Quarterly	FMoH/EPHI	250
		Provide relevant vaccine program for all health workers and supportive staffs	Ensures vaccination services for all staff	Establish vaccination program	Bi-annually	FMoH/EPHI	100
	Utilizing WHO, CDC & NIH guidelines, standards, practice and procedures.	Adopt or utilize WHO, CDC & NIH guidelines, standards, practice and procedures.	Activities managed according to WHO CDC and or NIH guidelines, standards, and procedures.	Presence of adopted guidelines, standards, and or procedures.	Annually	FMoH/EPHI	100
		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.	Well practice on drill exercise  Proper emergency management	Number of staff trained on drill exercise	Quarterly	FMoH/EPHI	100
8)	Establish M&E system for ICWM	Develop and disseminate M&E plan & tools for ICWM	To identify gaps and challenges	Number of M&E plan developed and implemented	Annually	FMoH/EPHI	500
		utilize M&E tools (tracking tools, facility audit, IPC checklist) ICWM M&E tools	To identify gaps and challenges	Number of M&E tools developed and	Biannually	FMoH/EPHI	100

S.N	Mitigation strategies	Activities	Desired outcome	Monitoring: performance indicators/ target of acceptance criteria	Time frame	Responsible body	Budget \$ (Proposed)
				implemented			
		Training, orientation and health workers induction on M&E tools and reporting	Properly managing M&E on ICWM	Number of health workers	Biannually	FMoH/EPHI	100
9)	Maintain the incinerators periodically	Perform preventive maintenance for the incinerators periodically	Well functional incinerators	Documented preventive maintenance record	Annually	FMoH/EPHI	1,000
10)	Risks associated with demotion of the existing incinerators						
10a	Avoidance of release of residue ash to the environment during demolition of the existing incinerators	<ul style="list-style-type: none"> <li>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.</li> <li>A suitably licensed waste collector will be used to collect, transport and dispose the chemical wastes to the designated treatment facility</li> </ul>	No risks associated with release of residual ash	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	During construction phase	EPHI AAEFCC The Decommissioning Company	Cost included in the decommissioning cost
10b	Minimizing airborne dust associated with the demolition on the existing incinerators	<ul style="list-style-type: none"> <li>Wet wiping of the surface to minimize airborne dust.</li> <li>The decommissioning and demolition work will be carried out in full containment</li> </ul>	No or minimized risk associated with airborne dust due to demolition activities	Decommissioning and demolition work carried out in full containment; adequate health and safety protection	During construction phase	EPHI AAEFCC The Decommissioning Company	Cost included in the decommissioning cost

S.N	Mitigation strategies	Activities	Desired outcome	Monitoring: performance indicators/ target of acceptance criteria	Time frame	Responsible body	Budget \$ (Proposed)
				measures in place. Appropriate waste collection procedure in place to collect, transport and dispose the chemical wastes to the designated treatment facility			
10c	Avoidance of the release of asbestos containing materials and chemical waste from demolition of the existing incinerators	<ul style="list-style-type: none"> <li>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.</li> <li>A suitably licensed waste collector will be used to collect, transport and dispose the chemical wastes to the designated treatment facility</li> </ul>	No risks associated with release of asbestos containing materials and chemical waste	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	During construction phase	EPHI AAEFCC The Decommissioning Company	Cost included in the decommissioning cost
10d	Avoidance risks associated with wastewater from demolition activities of the existing incinerators	<ul style="list-style-type: none"> <li>The floor drain in the incinerator room will be covered with a temporary seal during the decommissioning and demolition works.</li> <li>The top of the chimney would be sealed with polyethylene sheets at least twenty-four (24) hours before the works commence</li> </ul>	No risks associated with wastewater from demolition activities	Decommissioning and demolition work carried out in full containment; Appropriate waste collection procedure in place to collect, transport and dispose the	During construction phase	EPHI AAEFCC The Decommissioning Company	Cost included in the decommissioning cost

S.N	Mitigation strategies	Activities	Desired outcome	Monitoring: performance indicators/ target of acceptance criteria	Time frame	Responsible body	Budgets \$ (Proposed)
				chemical wastes to the designated treatment facility  adequate health and safety protection measures in place			
11)	Impact of air pollution due to waste incineration	Purchase new environmental friendly incinerator	A new environment friendly Pyrolytic incinerator purchased & installed	Pyrolytic incinerator installed	once	FMoH/EPHI	
			Signed agreement between supplier and EPHI for training, maintenance and supplying spare parts	Training and maintenance service provided	Annually	FMoH/EPHI	1,000
12)	Risk associated with Liquid Waste treatment plant and incinerator	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	<b>500.00</b>
		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
		The new liquid water treatment plant would be monitoring for proper functionality periodically	identified any defect or malfunction of liquid waste treatment plant	Record of preventive maintenance of liquid waste treatment plant	Quarterly	AAEFCC, EPHI	<b>500.00</b>
13)	Impact associated with final disposal of solid and liquid wastes	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
		Bottom ash would be managed separately from fly ash and other flue gas treatment	Avoid contamination of the bottom ash for its potential	Amount of bottom ash managed	Operation phase	AAEFCC, EPHI	-

S.N	Mitigation strategies	Activities	Desired outcome	Monitoring: performance indicators/ target of acceptance criteria	Time frame	Responsible body	Budges \$ (Proposed)
			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	Helps achieve a leaching level for metals and salts that is in compliance with the local environmental conditions at the place of use	Amount of bottom ash treated	Operation phase	AAEFCC, EPHI	-
		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	-
		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
		Waste disposal system would be monitored periodically	identified technical problems and technology updates	Periodical monitoring	Quarterly	AAEFCC, EPHI	2000.00
		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
<b>Total Cost</b>							<b>15,250.00</b>

### **3.6 Capacity Building and Training Plan**

The development and operation of the proposed BSL 3 National reference laboratory needs to have a strong Infection control and waste management system including 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 ICWMP implementation of the proposed project. 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.

In order to implement the ICWMP plan, EPHI staff would be trained and aware of good practices and procedures of infection control and waste management that are stipulated under this plan. 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 BSL 3 NRL complex staff to enhance their skills in infection control and Biosafety during the operational phases of the NRL BSL-3 laboratory. The budget for technical support and capacity building training will be **34, 000.00 USD**.

The Right attitudes for effective Infection Control and Waste Management originate from knowledge and awareness regarding the potential risk of health-care wastes and administrative procedures for handling these wastes. Apart from a general understanding of the requirements of ICWM, each category of personnel (researchers, laboratory scientist professionals, Biosafety officers, cleaners, waste handlers, Liquid waste treatment plant operators, incinerator operators, administrative staff etc.) needs to be trained. For the training to be successful and to lead to the desired objective, participants must become aware of the risks linked to healthcare waste management. Table 12 below highlight suggested training courses needed for effective implementation and monitoring of ICWMP.

**Table 11: Trainings Plan for Staff and Support Staff of BSL 3 NRL Complex**

Capacity Needs	Target Participant	Number of participants	Estimated Cost (Usd)
Training on Infection control and waste management	<ul style="list-style-type: none"> <li>Professionals working in in BSL 3 NRL Complex (BSL 3 Laboratory, PTPC, biobank Centre, Central Warehouse, and LEMC)</li> <li>Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators and other staff of the BSL 3 laboratory</li> </ul>	70 24	6,000.00
Training on OSHA and environmental safety	<ul style="list-style-type: none"> <li>Professionals working in in BSL 3 NRL Complex (BSL 3 Laboratory, PTPC, biobank Centre, Central Warehouse, and LEMC)</li> <li>Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators and other staff of the BSL 3 laboratory</li> </ul>	70 24	6,000.0
Training on biosafety and biosecurity	<ul style="list-style-type: none"> <li>Professionals working in in BSL 3 NRL Complex (BSL 3 Laboratory, PTPC, biobank Centre, Central Warehouse, and LEMC)</li> <li>Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators and other staff of the BSL 3 laboratory</li> </ul>	70 24	6,000.00
Training on emergency preparedness and response	<ul style="list-style-type: none"> <li>Professionals working in in BSL 3 NRL Complex (BSL 3 Laboratory, PTPC, biobank Centre, Central Warehouse, and LEMC)</li> <li>Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators and other staff of the BSL 3 laboratory</li> </ul>	70 24	6,000.00
Training on handling pathogenic and potentially lethal agents	<ul style="list-style-type: none"> <li>Professionals working in in BSL 3 NRL Complex (BSL 3 Laboratory, PTPC, biobank Centre, Central Warehouse, and LEMC)</li> </ul>	16	5,000.00
Training on use of MSDSs, safe work practices, and appropriate PPE	<ul style="list-style-type: none"> <li>Professionals working in in BSL 3 NRL Complex (BSL 3 Laboratory, PTPC, biobank Centre, Central Warehouse, and LEMC)</li> <li>Cleaners, waste transporters and handlers, incinerator operators, liquid waste treatment facility operators and other staff of the BSL 3 laboratory</li> </ul>	70 24	5,000.00
<b>Total</b>			<b>34, 000.00</b>



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## **Annexes**

### **Annex 1: 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, wards, and in all public areas.
- All non-risk HCW not designated for recycling shall be collected with the other municipal waste.
- Non-contaminated items that are designated for recycling shall be packed in specific black containers marked “Non-contaminated plastic, to be recycled” or white containers marked “Non-contaminated glassware, to be recycled.”
- Non-risk health care waste should be disposed of similarly to domestic garbage and food waste (burning, municipal waste collection, land fill, etc).

#### **Class 2: Clinical waste (non-sharp infectious waste)**

- All class 2 clinical waste shall be placed in yellow polyethylene bags (minimum 300 micron gauge) marked “Danger! Hazardous medical waste” and indicated with the international biohazard symbol.
- Bags shall be sealed with appropriate adhesive tape, removed, and replaced immediately when they are no more than three-quarters full.
- If available, yellow bins or containers shall be used—they must be systematically disinfected in a solution of 0.5% of sodium hypochlorite or Lysol every time they are emptied.
- All class 2 clinical HCW shall be buried in a protected pit or incinerated in double-chamber incinerators.
- In highly densely populated areas, centralized pyrolytic incinerators reaching 850°C and above shall be used.
- In minor HCFs in rural areas, class 2 clinical HCW should be buried in a simple protected pit when there is no risk of contaminating underground water. All pits must be fenced to prevent authorized access.
- Yellow containers for infectious clinical waste should be located in all wards and rooms where infectious waste could be produced.
- Infectious waste containers should never be placed in public areas.

#### **Class 3: Sharps**

- Safety boxes must be located in all rooms and wards within an arm's reach from where injections may be given.
- All class 3 sharps shall be placed in specific cardboard boxes called safety boxes, which are resistant to punctures and leakproof, designed so that items can be dropped in using one hand and so that no item can be removed.
- The safety box shall be colored yellow and marked "Danger!" or "Contaminated sharps." Yellow is conventionally accepted color and it is advisable to stick to this color. However, in the absence of yellow colored safety box, white ones can be used.
- The safety box shall be closed when three-quarters full.
- All disposable syringes and needles shall be discarded immediately following use.
- The needle shall not be recapped or removed from the syringe; the whole combination shall be inserted in to the safety box. In field situation where there is no safety box, one-hand recapping may be acceptable. However, this does not mean that one-hand recapping is recommended.
- Under no circumstances are used syringes, needles, or safety boxes to be disposed of in normal garbage or dumped without prior treatment.
- The method of choice for destruction of full safety boxes is incineration, preferably in an appropriate double-chamber (>850°C) incinerator.
- If such an incinerator is unavailable, alternative methods of sharp disposal may be used such as needle removers and sharps pits.
- Under exceptional circumstances, full safety boxes may be incinerated in small numbers by open burning in a fenced hole.

#### **Class 4: Pathology and Anatomical waste**

- In operation theatres, all class 4 anatomical waste and placentas shall be collected separately in a plastic or galvanized metal container with a tight-fitting cover.
- They should be transported using dedicated trolleys or carts. If transportation and disposal cannot be immediately ensured, anatomical waste should be stored in the mortuary.
- When a centralized incinerator is available they shall be incinerated. When low-temperature incinerators are used, anatomical waste, or large amounts of placentas, can be difficult to incinerate and will drastically reduce the performance of the system.
- If incineration cannot be performed, class 4 anatomical waste and placentas shall be buried at a sufficient depth (> 1m) inside the HCF compound.
- Wear utility gloves when handling and transporting anatomical waste and placenta.
- Remove utility gloves after handling waste. Wash and dry them daily and when visibly soiled.

- Wash and dry hands or use an antiseptic hand rub.

**Class 5: Hazardous pharmaceutical and cytotoxic waste**

- Hazardous pharmaceutical waste and cytotoxic waste shall be repacked in specific bags marked “Danger! Hazardous pharmaceutical and cytotoxic waste” and they shall be sent to the medical store department that shall ensure their disposal at the central level.
- Class 5 waste shall be incinerated in a pyrolytic incinerator at a minimum of 1,200°C, or it should be encapsulated and safely buried in a deep pit depending on the depth of local water tables.
- The bottom of the pit should be 1.5m away from the ground water table.
- Class 5 hazardous pharmaceutical wastes and cytotoxic waste containing heavy metals shall not be incinerated. For disposal of pharmaceutical wastes please refer to DACA’s guidelines.
- For this specific category of waste, inertization may be foreseen. In this case the residue can be disposed using landfill.
- Cytotoxic waste should never be discharged into the environment or natural water bodies like river, lakes, or landfills.

**Class 6: Highly infectious waste**

- Highly infectious waste from the medical diagnostic laboratory of the HCF—such as media and culture plates—shall be collected, preferably in leak-proof yellow bags suitable for autoclaving and properly sealed. It shall be autoclaved at a temperature of 121°C for at least 20 minutes at source, i.e. in the medical Diagnostic laboratory itself.
- Disinfected waste shall be collected and treated with class 2 hazardous HCW.
- If a distinct autoclave is not available at the medical diagnostic laboratory, highly infectious waste shall be disinfected in 0.5% solution of sodium hypochlorite and left overnight. It shall 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.
- Noninfectious radioactive waste, which has decayed to background level, shall follow the class 1 non-risk HCM stream, while infectious radioactive waste which has decayed to background level shall follow the class 2 clinical HCW stream.
- Liquid radioactive waste shall be discharged into the sewage system or into a septic tank only after it has decayed to background level in adequate tanks.

**Class 8: Waste with high contents of heavy metals (special hazardous waste)**

- Wastes with high contents of heavy metal should normally be treated in specific recovering industries. Alternatively, as for chemical waste, it should be encapsulated for handling and disposal.
- Wastes with high contents of mercury or cadmium shall never be incinerated because of the risk of atmospheric pollution with toxic vapors.
- In case of a spill from a broken thermometer or blood pressure equipment the following procedure is recommended: put examination gloves on both hands; collect all droplets of mercury with a spoon and place it in a small, closed container for disposal or reuse; disinfect and clean the area where the equipment was broken.
- Mercury is a potent neurotoxin, especially during fetal and infant development. Please follow appropriate guidelines for mercury disposal— it enters the environment when released in to water bodies and air, and thereby contaminating lakes, rivers, and streams, and polluting the ambient air.

**Class 9: Effluents**

- All effluents in HCFs shall be drained to a septic tank or cesspool for both storage and treatment in the compound of the HCF.
- If it is necessary to discharge the waste through municipal sewer line, all liquid infectious waste shall be discharged only after being treated according to WHO standards.
- Waste water from HCFs should not be released into the environment without treatment because they may contain various potentially hazardous components such as microbiological pathogens, hazardous chemicals, pharmaceuticals and radioactive isotopes. The proper treatment of waste water from HCFs is very expensive and cannot be currently foreseen in every HCF of Ethiopia. However, the basic steps described above should be applied to contribute to the reduction of the public health risk associated with liquid waste and waste water.



## Annex 2: Required Personal Protective Equipment (PPE) for Safe Waste Management at BSL 3 Laboratory

Waste Handlers and Incinerator operators should always have adequate personal protective equipment (PPE). PPE must be worn at all times when working with health care waste. It is important that the PPE is properly maintained and kept clean; it should not be taken home; and must remain at the health facility to avoid possible spread of infection to the community.

### Standard PPE generally includes:

- **Gloves:** Always wear gloves when handling health care waste. Puncture-resistant gloves should be used when handling sharps containers or bags with unknown contents. Heat-resistant gloves should be worn when operating an incinerator
- **Boots:** Safety boots or leather shoes provide extra protection to the feet from injury by sharps or heavy items that may accidentally fall. Boots must be kept clean.
- **Overalls:** Overalls should be worn at all times.
- **Goggles:** Clear, heat-resistant goggles can protect the eyes from accidental splashes or other injury.
- Mouth respirators
- **Helmet (for incinerator operators):** Helmets protect the head from injury and should be worn at all times during the incineration process.

A policy for the management of health care waste cannot be effective unless it is applied carefully, consistently and universally. It is also important the provision of PPE for waste handlers. It is through training that standardization of waste handling practices and its management can be achieved. See table 11 for the resource requirement for implementing the ICWMP for the BSL 3 laboratory

**Table 12: Resource/PPE required for the provision of the ICWMP for BSL 3 laboratory**

S.N	Equipment (PPE) Required	Quantity	Unity Price (USD)	Total Price (USD)	Responsible Institutes
1.	Eye and Face protection	.25	20	500	EPHI, MOH,
2.	Head protection	25	10	250	EPHI, MOH,
3.	Foot protection	25	40	1,000	EPHI, MOH,
4.	Heavy duty gloves	300	3	900	EPHI, MOH,
5.	Mask N95 & others	250	10	2,500	EPHI, MOH,

6.	Gown (fully protection)	25	100	2,500	EPHI, MOH,
<b>TOTAL</b>				<b>7,650.00</b>	

## Health Worker Safety Measures

### Hand hygiene

Running Water and soap should be available to ensure clean hands after handling HCW. Hand washing is one of the oldest, most well-known methods of preventing disease transmission. HCW handlers and incinerator operators should always wash their hands after handling HCW.

### Medical examinations

Healthcare waste handlers and incinerator operators should be medically examined prior to initial employment and undergo regular medical examinations every 6 months. They should also be immunized for Tetanus and Hepatitis B Virus.

## Annex 3: Guideline for Waste Treatment and Disposal

Proper treatment and disposal of healthcare waste is necessary to ensure that its impact on the environment and human health is minimized or eliminated, and the following main tasks should be included for waste treatment:

- Among all the current existing technologies for the treatment and disposal of HCW, the most appropriate technology shall be applied. This should be the most reliable, affordable, and sustainable technology in accordance with the technical, human and financial resources of each HCF. This technology should also minimize the immediate public health risks associated with ICWM with the lowest impact on the environment.
- Several methods are appropriate for infectious waste treatment, depending on the type of waste material. These treatment methods shall include one of the following options or combination of options: steam sterilization, incineration, thermal inactivation, gas/vapor sterilization, chemical disinfection, sterilization by irradiation, or electromagnetic radiation. For additional waste management options please refer to Annex VII).
- Burning and low-, medium-, and high-temperature incineration may be considered the most practical technology for disposal of hazardous waste. In densely populated areas, large quantities of hazardous HCW shall not be incinerated at temperatures lower than 850°C.

- After treatment, the wastes or their ashes should be disposed of by discharge into sanitary sewer systems (for liquid or ground waste), or by burial in sanitary landfills or simple pit

**Table Recommended treatment methods of infectious wastes**

S.n	Type of infectious waste	Steam sterilization	Incineration	Thermal inactivation	Chemical disinfection
1.	Isolation wastes	√	√	√	
2.	Cultures and stocks of infectious agents and associated biologicals	√	√	√	√
3.	Human blood and blood products	√			√
4.	Pathological wastes	√	√		
5.	Contaminated sharps	√	√		
6.	Carcasses and parts	√	√		

### **I. Steam sterilization (autoclaving)**

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

The following guidelines should be included for steam sterilization (autoclaving):

- Autoclaves used to disinfect waste will be used only for waste treatment—never for disinfection of instruments to be used clinically. Autoclaves used for waste must be located in a room separate from autoclaves used for clinical disinfection.
- Containers that can be used effectively in steam sterilization include plastic bags, metal pans, bottles, and flasks. High-density polyethylene and polypropylene plastic should not be used in this process because they prevent steam penetration to the waste load.
- Heat-labile plastic bags allow steam penetration of the waste but may crumble and melt. If heat-labile plastic bags are used, they should be placed in another heat-stable container that allows steam penetration (e.g., strong paper bag), or they should be treated with gas/vapor sterilization.
- The following precautions should be taken when using steam sterilization:
- Plastic bags should be placed in a rigid container before steam treatment to prevent spillage and drain clogging.

- To facilitate steam penetration, bags should be opened and caps and stoppers should be loosened immediately before they are placed in the steam sterilizer.
- Care should be taken to separate infectious waste from other hazardous waste.
- Waste that contains drugs, toxic chemicals, or chemicals that would be volatilized by steam should not be steam-sterilized.
- Persons involved in steam sterilizing should be trained in handling techniques to minimize personal exposure to hazards from infectious wastes. Some of these techniques include: use of personal protective equipment/materials, minimization of aerosol formation by using disinfectant chemicals, prevention of waste spillage during autoclave loading and unloading, prevention of burns from handling hot containers, and management of spills.
- The autoclave temperature should be checked with a recording thermometer or sterilization indicator strip to ensure that the proper temperature is being maintained for substantial periods during the cycle.
- Steam sterilizers should be routinely inspected and serviced, and the process should be routinely monitored to ensure that the equipment is functioning properly. Autoclaves and steam sterilizers should be serviced and maintained periodically following manufacturer instruction.
- An alternative treatment method such as incineration should be used on high-density wastes (e.g., large body parts, large quantities of animal bedding or fluids, etc.) because they inhibit direct steam penetration and require longer sterilization times.

## **II. Burning and Incineration**

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

The following guidelines should be included for incineration:

- Incineration should be used for disposal of pathological wastes such as tissues and body parts.
- Incineration should be used to render contaminated sharps unusable.
- The principal factors affecting incineration such as variations in waste composition, the waste feed rate, and the combustion temperature should be considered in order to maintain efficiency of incinerating infectious wastes. Proper operating procedures must be followed.

- Infectious wastes containing drugs should be disposed of in an incinerator that provides high temperatures and sufficient length of cycle for the complete destruction of these compounds. Incineration of such wastes should be done following DACA's guidelines.
- The effectiveness of the incinerator in disposing and destructing of chemical wastes should be documented and assessed before use, if applicable.
- Persons involved in incineration must wear protective clothing and should be trained in handling techniques to minimize personal exposure to hazards from infectious wastes. Some of these techniques include the use of personal protective equipment and materials, prevention of waste spillage during incinerator loading, and the management of spills.
- The following materials shall not be burned or incinerated due to the toxic emissions they produce: PVC plastics, photographic and x-ray materials, mercury thermometers, batteries and other items containing heavy metals, and aerosol cans or sealed vials. These materials can, however, be safely be managed and disposed of through burial techniques.
- All incinerators or burning areas must be fenced to prevent access by the community or animals. They should be located away from houses and crops.
- All incinerators should be inspected and maintained by a qualified person on a regular basis.

### **III. Thermal inactivation**

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

The following guidelines should be included for thermal inactivation:

- After treatment, the contents should be discharged into the sewer or landfills in a manner that complies with federal and local requirements.
- Solid infectious waste should be treated with dry heat in an oven, which is usually electric.
- Persons involved in thermal inactivation should be trained in handling techniques to minimize personal exposure to hazards from infectious wastes. Some of these techniques include the use of personal protective equipment/materials, prevention of waste spillage during thermal inactivation loading and unloading, the prevention of burns from handling hot containers, and the management of spills.

### **IV. Gas/vapor sterilization**

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

The following guidelines should be included in gas/vapor sterilization:

- Gas/vapor sterilization should be used with caution since it is a suspected human carcinogen, because ethylene oxide may be adsorbed on the surface of treated materials, and because the potential exists for worker exposure when sterilized materials are handled.
- Persons involved in gas/vapor sterilization should be trained in handling techniques to minimize personal exposure to hazards from infectious wastes and handling of sterilized materials. Some of these techniques include the use of personal protective equipment and materials, the prevention of waste spillage during gas/vapor sterilization loading and unloading, the prevention of burns from handling hot containers, and the management of spills.

#### **V. Chemical disinfection/high-level disinfection (HLD)**

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

The following guidelines should be included for chemical disinfection:

- The type of microorganism and disinfectant should be considered when using chemical disinfection. The best chemicals appropriate for disinfection are chlorine and glutaraldehyde. It is advisable to follow manufacturer instruction for concentration of the chemicals and contact time. Different concentration and contact time is recommended for different chemicals by different manufacturers. However, the best and most common disinfectant is the use of 0.5% chlorine solution for 10 minutes. Other relevant factors such as temperature, pH, mixing requirements, and the biology of the microorganism should be considered.
- Ultimate disposal of chemical waste should be in accordance with scientific technical procedures suggested by WHO so as to protect users, the community, and the environment.
- Persons involved in chemical disinfection should be trained in handling techniques to minimize personal exposure to hazards from infectious wastes and handling of sterilized materials. Some of these techniques include the use of personal protective equipment and materials, the prevention of exposure to pathogenic organism, the prevention of waste spillage during chemical disinfection loading and unloading, the prevention of burns from handling hot containers, the management of spills, and methods of handling sterilized materials.

## **VI. Final disposal**

To fulfil Best Environmental Practices an Environmental and Social Impact Assessment (ESIA) will precede commencement of any civil works aimed at installation of incinerators in both primary and secondary healthcare facilities. The following guidelines should be included for final disposal:

- The recommended types of final disposal methods are: conventional sewer system for discharge of treated liquids and grounded solids; or landfill disposal of treated solids and incinerator ash.
- EPA and MOH at all levels shall ensure that only treated infectious wastes are buried in landfills.
- Burial sites should be fenced to prevent access by community members or animals. Only hazardous health care waste should be buried. Burial should not be used in areas with high water tables. The bottom of the pit should be at least 1.5 meters higher than the groundwater level.
- Facilities should secure the services of reputable waste handlers to ensure, to the extent possible, that final disposal of hazardous waste is performed according to applicable federal and local regulations.

## **VII. Burial pits**

Protected burial pits are an acceptable—and perhaps the most appropriate—disposal option for infectious wastes in rural health care facilities. Disposal Procedural Steps

- Provide secured appropriately lined pits for final disposal of incineration ash.
- Transportation of incineration ash and non-hazardous and treated hazardous waste (that has been rendered non-infectious) to engineered designated land fill sites.

## **Annex 4: Procedures for handling and disposal of health care waste**

### **General waste**

General waste is non-hazardous and under normal circumstances poses no health risk. It includes paper, packaging, leftover foods, boxes, glass, plastics, etc.

- General waste is immediately placed in the general waste bin (black) by the person generating it.
- Waste handlers collect general waste daily, using a wheelbarrow/cart designated for general waste.
- If offsite disposal is available, the waste is stored until the scheduled collection day.
- If incinerated onsite, the general waste is taken directly to the incinerator on days when the incinerator is being operated.
- If the incinerator is not operating on that day, the waste handler stores general waste in a covered, secure location until final disposal (*waste should not be stored for more than 2 days*).
- Incinerator operator destroys general waste according to schedule.
- Incinerator operator removes ash after the incinerator has cooled down completely, and disposes of it in an ash pit.

### **Food waste**

Food waste is part of general and non-risk waste that refers to leftover foods and food products.

- Food waste is immediately placed in the designated bin.
- Waste handler collects and disposes of food waste immediately after meal times.
- If offsite disposal is practiced, food waste should only be stored for up to 1 day.
- If no on-site disposal, waste handler buries food waste daily. It is highly recommended that food waste should be composted. (When burying, strictly follow the guidelines on burying waste)

### **Infectious Waste**

Infectious waste is a waste material that has been in contact with blood and/or body fluids. Due to the presence of blood and blood products, such wastes are regarded as infectious waste and can have and transmit microorganisms to susceptible person. It includes contaminated gauze, dressings, cultures, IV lines, used gloves, anatomical wastes, placenta, tissues, etc.

- Health care provider immediately places infectious waste in the infectious waste bin with liner bag (yellow)
- Waste handlers collect waste every day or when the liner bag is full using a wheelbarrow/cart designated for infectious waste



- On days when the incinerator is being operated, the infectious waste is taken directly to the incinerator or it shall be disposed using burial technique.
- If the incinerator is not operating on that day, the waste handler stores infectious waste in a covered secure location until final disposal. (*Infectious waste should be disposed of within 2 days, but placenta and anatomical waste should be disposed on daily basis*).
- Incinerator operator destroys infectious waste according to schedule.
- Incinerator operator removes ash after the incinerator has cooled down completely, and disposes of it in an ash pit
- In settings where an incinerator is not available, waste handlers take infectious waste to the facility disposal site and bury it in a secured waste pit.
- In settings where an incinerator is not available, waste handlers take anatomical waste like placentas to a placenta pit for disposal.
- Waste handlers decontaminate the container and return it to be reused.

### **Sharps**

Sharps are sharp material and equipment that are disposed after being used (e.g., used syringes, needles, lancets, blades, scalpels, broken glasses, etc.).

- Injection providers immediately places used syringe in a safety box.
- Injection providers closes safety box when it is  $\frac{3}{4}$
- Waste handlers collect filled safety boxes for storage in a secure, covered, dry location awaiting final disposal. full and obtains a new safety box.
- Waste handlers transports safety boxes to incineration sites using a wheelbarrow/cart designated for transport of infectious waste.
- Incinerator operators destroy safety boxes according to schedule (safety boxes should be destroyed within one week).
- Incinerator operators remove ash after the incinerator has cooled down completely, and disposes of it in an ash pit.

### **Annex 5: 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.



**Annex 6: Sample waste collection and incineration/disposal record**

Date dd/mm/yy	Waste collected estimated in kg				Origin of waste (Ward/Dept., etc)		Name & Sign. of person depositing waste	Name & Sign of Supervisor
	Sharps (kg)	Infectious (kg)	Highly Infectious	General waste (kg)	Means of transport to Disposal Site	Incineration/ burning of waste		

## **Annex 7: Code of practice and Health and medical surveillance 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 and 2.

### **a. Code of practice**

The code of practice for basic laboratories – Biosafety Levels 1 and 2 applies except where modified as follows.

1. The international biohazard warning symbol and sign (see Figure 1) displayed on laboratory access doors must 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.
2. Laboratory protective clothing must 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 must not be worn outside the laboratory, and it must 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).
3. Open manipulations of all potentially infectious material must be conducted within a biological safety cabinet or other primary containment device.
4. Respiratory protective equipment may be necessary for some laboratory procedures or working with animals infected with certain pathogens.

### **b. Health and medical surveillance**

The objectives of health and medical surveillance programs for basic laboratories –

Biosafety Levels 1 and 2 also apply to containment laboratories – Biosafety Level 3, except where modified as follows:

1. Medical examination of all laboratory personnel who work in containment laboratories BSL 3 is mandatory. This should include recording of a detailed medical history and an occupationally-targeted physical examination.
2. 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.

- This card should a picture of the card holder, be wallet-sized, and always be carried by the holder.
- The name(s) of the contact persons to be entered will need to be agreed locally but might include the laboratory director, medical adviser and/or biosafety officer.

### **c. Laboratory design and facilities**

The laboratory design and facilities for basic laboratories – Biosafety Levels 1 and 2 apply except where modified as follows:

- a. The laboratory must 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 should 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 should be water-resistant and easy to clean. Openings through these surfaces (e.g. for service pipes) should be sealed to facilitate decontamination of the room(s).
- d. The laboratory room must be sealable for decontamination. Air-ducting systems must be constructed to permit gaseous decontamination.
- e. Windows must be closed, sealed and break-resistant.
- f. A hand-washing station with hands-free controls should be provided near each exit door.
- g. There must be a controlled ventilation system that maintains a directional airflow into the laboratory room. A visual monitoring device with or without alarm(s) should 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 must 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 must 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 should be given to the installation of audible or clearly visible alarms to notify personnel of HVAC system failure.
- i. All HEPA filters must be installed in a manner that permits gaseous decontamination and testing.

- j. Biological safety cabinets should 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, must 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 should be available in the containment laboratory. If infectious waste has to be removed from the containment laboratory for decontamination and disposal, it must be transported in sealed, unbreakable and leak proof containers according to national or international regulations, as appropriate.
- m. Backflow-precaution devices must be fitted to the water supply. Vacuum lines should be protected with liquid disinfectant traps and HEPA filters, or their equivalent. Alternative vacuum pumps should also be properly protected with traps and filters.
- n. The containment laboratory – Biosafety Level 3 facility design and operational procedures should be documented.

#### **d. 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 must be conducted within a biological safety cabinet or other primary containment device. Consideration should 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.

## Annex 8: EPHI Specification requirement for Incinerator

**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.

Type	Pyrolytic- Hot Medical Waste Disposing Machine
Technology	Pyrolytic
Operation Condition	8-16 Hr /day
Controls	Built in data recording
Incinerator /Primary Combustion Chamber	<b>Type:</b> continuous loading
	<b>Capacity/Burn rate per hour</b> 50 kg/hr
	<b>Temperature:</b> $\geq 900$ °C
	<b>Material:</b> <b>External-</b> 3 layers <b>Internal lining:</b> 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	<b>Type:</b> horizontal/vertical
	<b>Temperature:</b> $\geq 1200$ °C
	<b>Residence time of gases :</b> $\geq 2$ seconds
	<b>Material</b> <b>External-</b> Low thermal mass insulation 14-30 °C <b>Internal lining:</b> 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
	<b>Auxiliary device:</b> Water level gauge, pressure sensor, PH sensor..etc
	<b>Auxiliary device:</b> Fuel cutoff device
Waste feeding mechanism	Automatic pneumatic/hydraulic waste loading system or conveyor belt , capacity > 650L at a time
Chimney (Stack)	<b>Type:</b> Vertical type
	<b>height:</b> $\geq 7$ meter
	<b>Material:</b> Fireproof cast, stainless steel
Wet scrubbing system	Vertical sprat tower with baffles or packing inside
Gas emission	Reduction of Pollutant gas SO <sub>2</sub> , 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 <sup>3</sup>
OUTPUT	ASH -Max $\leq 5\%$ of original waste size
	GAS- SMOKELESS,ODORLESS
Emission standard	WB emission standards as follow: Total Particulate Matter (PM)            10 mg/Nm <sup>3</sup> Total organic carbon (TOC)                10 mg/Nm <sup>3</sup> Hydrogen chloride (HCl)                    10 mg/Nm <sup>3</sup> Hydrogen fluoride (HF)                      1mg/Nm <sup>3</sup> Sulfur dioxide (SO <sub>2</sub> )                        50 mg/Nm <sup>3</sup>



	Carbon monoxide (CO) 50 mg/Nm <sup>3</sup> NO <sub>x</sub> 200 mg/Nm <sup>3</sup> Mercury (Hg) 0.05 mg/Nm <sup>3</sup> Cadmium + Thallium (Cd + Tl) 0.05 mg/Nm <sup>3</sup> Sb, As, Pb, Cr, Co, Cu, Mn, Ni and V 0.5 mg/Nm <sup>3</sup> Polychlorinated dibenzodioxin and dibenzofuran (PCDD/F) 0.1 Ng/Nm <sup>3</sup> 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"> <li>- Local agent or branch in Ethiopia</li> <li>- Training for users as well as for EPHI maintenance staff on preventive maintenance</li> <li>- Fuel tanker with a minimum capacity of 2500 litre (material type need to be specified)</li> <li>- The bidder should be willing to sign at least a five years' service and maintenance agreement with the client (EPHI)</li> </ul>

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: ≤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 ≤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 SO2, 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,</p> <p>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

## Annex 9: 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 &amp; coli ( the causes of gastro-enteritis in animals &amp; humans)</i>	Newly added May 27
7	<i>Clostridium spp (Cl. Chauvoei( Blackleg) , Cl . Perfuringen,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>	
	<b>Virus</b>	
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 Diaharroe 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	<b>MERS-COV</b>	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**

### **Amount allowed to transport**

1	<i>Abrin</i>	100 mg
2	<i>Aflatoxins</i>	
3	<i>Botulinum neurotoxin</i>	0.5 mg
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>	100 mg
8	<i>Saxitoxin</i>	100 mg
9	<i>Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxins (formerly known as Staphylococcus enterotoxin F)</i>	5 mg
10	<i>T-2 Toxin</i>	1000 mg
11	<i>Tetrodotoxin</i>	100 mg
12	<i>Shiga toxin</i>	

## **Annex 10: 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.
2. **Ahmed Mohamed**, (BSc, MPH), Assistant researcher, Occupation health and safety and public health expert, Ethiopian Public Health Institute, Addis Ababa, Ethiopia.
3. **Yeabkal Daniel**, (BSc, MSc) Associate researcher, Biosafety and Biosecurity expert
4. **Daniel Abera**, (BSc, MSc), Researcher, Ground water quality modeling expert, Ethiopian Public Health Institute, Addis Ababa, Ethiopia
5. **Kirubel Tesfaye**, (BSc, MSc), Researcher, Water quality expert, Ethiopian Public Health Institute, Addis Ababa, Ethiopia
6. **Melaku Gizaw**, (BSc, MSc), Associate researcher, Environmental analytical chemist, Ethiopian Public Health Institute, Addis Ababa, Ethiopia.
7. **Mesaye Getachew**, (BSc, MSc), Associate researcher, Environmental chemist, Ethiopian Public Health Institute, Addis Ababa, Ethiopia.
8. **Moa Abate**, (BSc, MSc), Associate researcher, Occupation health and safety expert, Ethiopian Public Health Institute, Addis Ababa, Ethiopia.
9. **Tsigereda Assefa**, (BSc, MSc), Associate researcher, Environmental science and technology expert, Ethiopian Public Health Institute, Addis Ababa, Ethiopia.
10. **Abel Weldetinsae**, (BSc, MSc) Associate researcher, Environmental pollution and sanitation expert, Ethiopian Public Health Institute, Addis Ababa, Ethiopia.
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.

## **Annex 11: A 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.



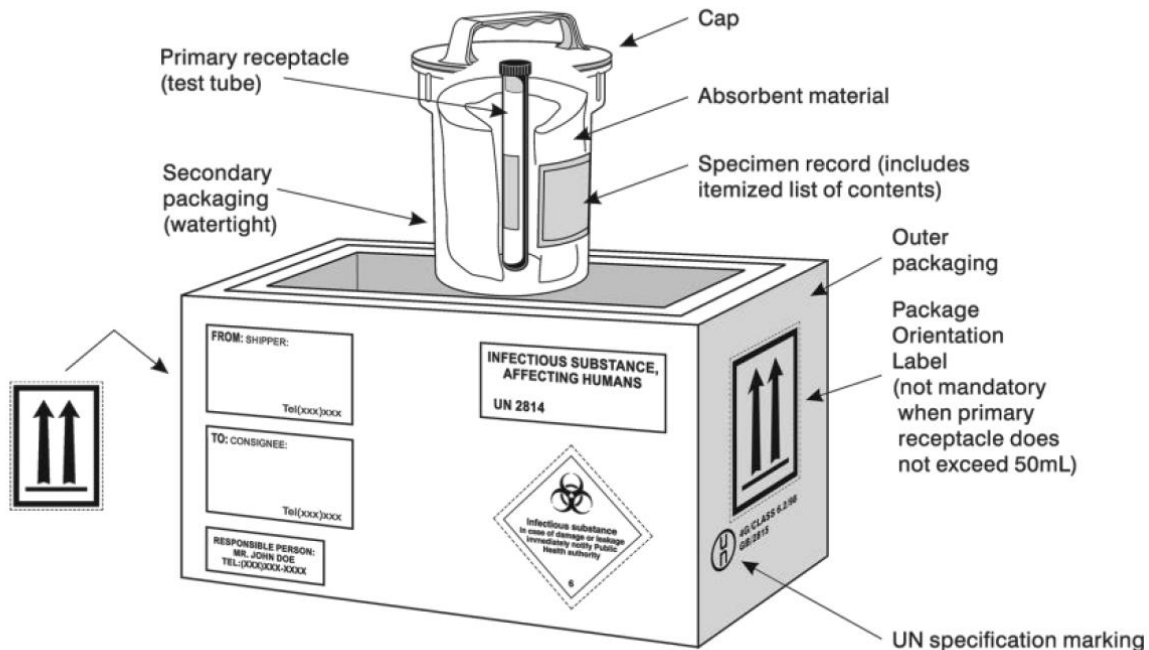


Figure 1. Example of triple packaging system for the packaging and labelling of Category A infectious substances  
**Marking**

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

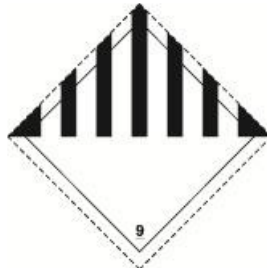
There are two types of labels:

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						
<b>Shipper</b> Dr XY Orange, tel 0789 456 123 Childrens' hospital 4 Splendid Street 12345 Beautycity Niuecountry			<b>Air Waybill No.</b> 543 7654 9876 <b>Page</b> 1 of 1 Pages <b>Shipper's Reference Number</b> (optional)			
<b>Consignee</b> Dr AB Normal, tel 03210 987 4568 Virobactung Laboratories 6 Many Way 98765 Myplace Hercountry						
<i>Two completed and signed copies of this declaration must be handed to the operator.</i>						
<b>TRANSPORT DETAILS</b> This shipment is within the limitations prescribed for: (Delete non-applicable)			<b>WARNING</b> Failure to comply in all aspects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.			
<input type="checkbox"/> PASSENGER AND CARGO AIRCRAFT		<input checked="" type="checkbox"/> AIRCRAFT		<b>Airport of Departure:</b> Amleaving		<b>Shipment Type</b> (Delete non-applicable) <input type="checkbox"/> NON-RADIOACTIVE <input checked="" type="checkbox"/> RADIOACTIVE
<b>Airport of Destination</b> Willgetthere						
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	
<b>Additional Handling Information</b> 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.				<b>Name/Title of Signatory</b> Dr XY Orange Goods Dispatch <b>Place and Date:</b> Beautycity 18 June 2010 <b>Signature</b> (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

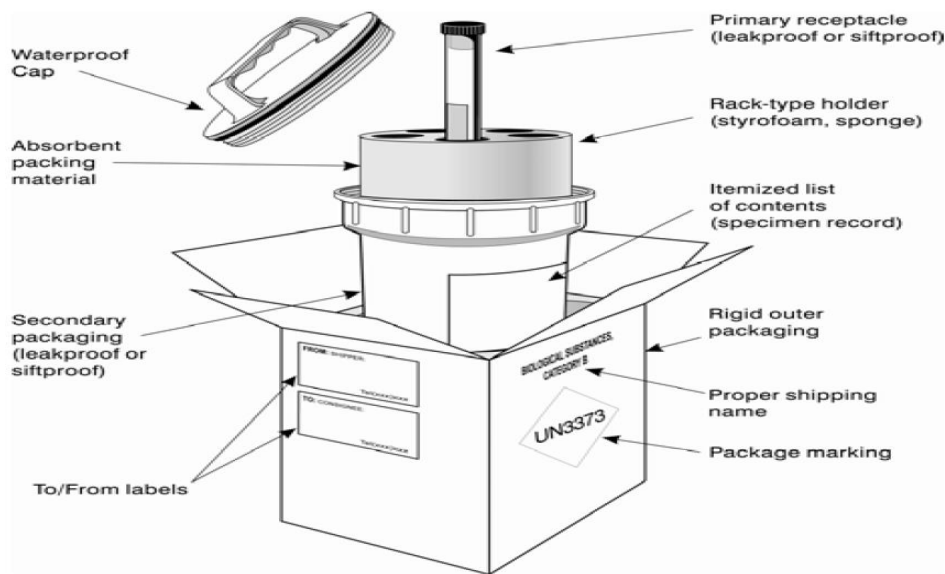
**Category B:** An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373

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:

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4. Apply the disinfectant concentrically beginning at the outer margin of the spill area, working towards the centre.
5. After about 30 min, clear away the materials. If there is broken glass or other sharps are involved, use a dustpan or a piece of stiff cardboard to collect the materials and deposit them into a puncture-resistant container for disposal.
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### **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.

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### **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.

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- 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.