Zambia National Public Health Institute
Ministry of Health
Lusaka, Zambia

INFECTION CONTROL AND WASTE MANAGEMENT PLAN

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ABREVIATIONS AND ACRONYMS

AFB – Acid-Fast Bacilli
BMBL – Biosafety in Micro Biological and Biomedical Laboratories
BMW – Bio Medical Waste Management
BSC – Biological Safety Cabinets
BSL – Biosafety Level
BSL-2 – Biosafety Level 2
BSL-3 – Biosafety Level 3
CDC – Centre for Disease Control and Prevention
EMA – Environmental Management Act
HCW – Health-Care Waste
HEPA – High Efficiency Particulate Air filter
HPCZ – Health Professions Council of Zambia
ICWMP – Infection Control and Waste Management Plan
IEC – Information, Education and Communication
IPC – Infection and Prevention Control
MOH – Ministry of Health
MOJ – Ministry of Justice
NBA – National Biosafety Authority
NHRA – National Health Research Authority
OHS – Occupational Health and Safety
PEP – Post Exposure Prophylaxes
"PEP" rule – (People, Environment, and Property) rule
PHL – Public Health Laboratory
PHEOC – Public Health Emergency Operations Centre
PLC – Programmable Logic Control
PPE – Personal Protective Equipment
SOP – Standard Operating Procedures
WHO – World Health Organisation
ZNPHI – Zambia National Public Health Institute
ZNPHL – Zambia National Public Health Laboratory
ZEMA – Zambia Environmental Management Agency

CHAPTER 1: INTRODUCTION

The Public Health Laboratory (PHL) is a facility that focuses on diseases and the health status of population groups. It forms the backbone of a national laboratory network on alert to respond to novel strains of disease, natural disasters, chemical spills, foodborne outbreaks and other health emergencies. It also provides emergency response support, perform applied research, and provides training for laboratory personnel.

The objective of the ZNPHL is to carry out limited diagnostic testing, reference testing, and disease surveillance ranging from rabies and dengue fever to radiological contaminants, genetic disorders in new-borns and terrorist agents while preventing the spread of infection among laboratory staff in the laboratory and to the general public.

It is in this regard that the Zambia National Public Health Institute (ZNPHI) is developing a plan that will enhance infection prevention and waste management in the PHL. An infection prevention and waste management plan is fundamental for the PHL because it will ensure compliance to Infection and Prevention Control Guidelines (IPC).

1.1 Infection and Prevention Control Measures

In the operations of the ZNPHL, the following measures will be put in place to protect staff and the general public;

1) Availability of laboratory equipment and Standard Operating Procedures (SOP) (bio safety manuals and other guidelines).
2) Availability of appropriate Personal Protective Equipment (PPE) and waste management system.
3) Provision of appropriate immunization and Post Exposure Prophylaxes (PEP).
4) Monitoring occurrence of laboratory infections.
5) Provision of trained and competent human Resource.

1.2 Policy

In the operation of the ZNPHL, appropriate laboratory facilities, functional equipment, safe working environment, and competent trained human resource will be provided.

1.3 Guidelines

Standard safety precautions shall always be followed by laboratory staff/workers when obtaining and working with specimens. PPE shall be used appropriately and consistently as outlined in the facility safety manual.

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CHAPTER 2: BIOSAFETY LEVEL 3 (BSL3)

Biosafety Level 3 (**BSL-3**) is the recommended biosafety level for containment of agents or toxins that are likely to cause serious or fatal disease in humans and animals. Work at **BSL-3** requires enhanced facility design (with ventilation features to accommodate the safe handling and containment of level 3 pathogens) operational controls and special practices. The **BSL-3** facility's equipment, testing documents, architectural and engineering plans shall comply with all the relevant requirements stipulated by law. This will ensure compliance with the 2017 World Health Organisation (WHO) - Infection and Prevention Control Guidelines (IPC) guidelines, the 2011 Environmental Management Act (EMA), and the 2013 Environmental Management (Licensing) Regulations (which addresses waste water management, waste management, pesticides and toxic substances as well as ozone depletion substances). The Standard Operating Procedures (SOPs) specific to the Zambia National Public Health Laboratory and the annual containment verifications will be reviewed by Health Professions Council of Zambia (HPCZ), while research protocols will be reviewed and approved by the National Health Research Authority (NHRA).

Below is an outline of the general requirements for the **BSL-3** facilities at the Zambia National Public Health Laboratory. Additional requirements with regard to Select Agents and Select Agent Facility Documentations are addressed in the Institute-Specific Laboratory Biosafety Manuals.

2.1 Personal Protective Equipment (PPE) and Infection Prevention Practices

1) Laboratory coats, appropriate shoes and fluid resistant gowns shall be worn by all laboratory staff during specimen collection, handling and testing. Laboratory gowns/aprons shall not be worn outside the laboratory.
2) Laboratory personnel shall ensure that contaminated gloves are taken off and disposed accordingly before touching/handling equipment such as the telephones or computers.
3) All persons handling blood and body fluid specimens or items/surfaces soiled with blood or body fluids shall wear gloves, gowns and protective eyewear.
4) When carrying out procedures that shall be likely to generate splashes of blood or body fluids, face protection shall be used to prevent exposure of mucous membranes to the mouth, nose and eyes
5) Eating, drinking, smoking, donning of Jewellery and application of cosmetics shall not be permitted in the laboratory. Oral and ocular contact with any surface, capable of transmitting infectious agents is prohibited.

6) All specimens of blood and body fluids shall be collected and transported in appropriate transportation package. Triple packaging will be use as applicable and specimen will be stored and transported as per approved local and international guidelines (annex 3).
7) Mouth pipetting shall be strictly prohibited. Mechanical pipetting devices shall be used for manipulating all liquids in the laboratory.
8) Unfixed, unstained slides shall be considered contaminated and shall be handled using PPEs.

2.2 Prevention of Aerosols and Droplets

Handling of liquids or dry powders may generate aerosols or droplets in the ZNPHL. In practice, high-energy procedures, such as centrifuging, vortexing and mixing, produce respirable aerosols that stay airborne for extended periods and are small enough to be inhaled, while low-energy procedures, including opening containers and streaking plates, produce droplets that settle quickly on surfaces, skin, and mucous membranes.

Centrifuge Precautions:

1) Centrifugation shall be performed under conditions that prevent aerosolization. Using PPEs is recommended when operating centrifuges.
2) Laboratory surfaces/work stations shall be constructed to allow for the easy and complete cleaning and disinfection of surfaces.
3) All unused specimens shall be discarded as medical infectious/contaminated waste or poured down the contaminant sink/sewer as outlined in the laboratory waste management SOP.
4) All workstation surfaces shall be cleaned with an appropriate/approved disinfectant at the end of each shift or as needed or as indicated in the biosafety manual.
5) Employees who have exudative lesions or weeping dermatitis shall report to their supervisors or to the occupational health programs and refrain from all direct patient care.

2.3 Microbiology

1) Except for hard to get specimens e.g. spinal fluid, pleural fluid, and all specimens that do not meet the acceptance criteria as outlined in the sample reception SOP shall be discarded immediately.
2) All positive cultures shall be processed in the biological cabinet and proper containment measures shall be followed.
3) In the case of Mycobacteria, processing of all specimens for Acid-Fast Bacilli (AFB) shall be done in the recommended biological safety cabinet, N95 masks shall be worn.

4) All procedures involving manipulation of fungus cultures or on moulds isolated from cultures shall be performed in the biological cabinet (transfers, smears, wet preps, etc.).

2.4 Equipment

1) Non-recyclable equipment and supplies shall be discarded immediately after use.
2) Recyclable equipment and supplies shall be decontaminated as outlined in the Equipment Disinfection SOP.
3) All medical contaminated/infectious waste shall be autoclaved and removed for disposal by incineration or burial. Waste containers shall be covered during transport. They shall be cleaned and disinfected as necessary.

2.5 Blood

The ZNPHL shall provide functional and safe blood for culture media preparation as will be outlined in the ZNPHL biosafety manual.

2.5.1 Safety Guidelines

- Standard precautions shall always be practiced by laboratory staff/workers, such as hand hygiene and the use of PPEs shall be stressed; clean lab coats shall be worn when delivering blood; and clean lab coats may be worn out of the department.
- Blood products shall be screened for infectious agents according to national and international standards. Blood shall be checked and screened for among other things:
    - ABO blood group
    - Rh type
    - Syphilis (RPR)
    - Hepatitis B
    - Hepatitis C
    - HIV

CHAPTER 3: CONTAINMENT MEASURES FOR BSL3 LABORATORIES

The word "containment" is used to describe safe methods for handling and maintaining infectious agents in the laboratory environment. The ZNPHI will put measures in place to reduce or eliminate exposure of laboratory workers, other staff at ZHPHI, and the outside environment to potentially hazardous agents. Containment in the ZNPHL will be achieved by application of layered containment principles, with the aim of preventing exposure of laboratory workers to a pathogen or the inadvertent escape of a pathogen from the laboratory. There are four important fundamentals in containment; administrative controls, work practices, personal protective equipment, and facility design.

3.1 Primary Containment

This refers to the protection of laboratory personnel and the immediate laboratory environment from exposure to infectious agents by ensuring good microbiological techniques as well as use of appropriate safety equipment, such as the Biological Safety Cabinets (BSC), fume hoods and other engineering devices used by laboratory personnel while working with a biological hazard.

3.2 Secondary Containment

Secondary containment is designed to protect the laboratory's external environment from exposure to infectious materials by combining facility design and operational practices. The appropriate combinations of these elements are usually determined by the risk evaluation of the work to be done with a specific agent.

3.3 Containment Measures

The ZNPHI laboratory workspace will be separated from any other activities in the same building, air and extract air to the laboratory will be double filtered on extract air using the High Efficiency Particulate Air (HEPA) filter or equivalent. Biological materials will include, but not limited to:

1) Infectious microorganisms such as virus, bacteria, rickettsia, fungi, parasite, prion, etc., and the toxins derived from such organisms that can cause disease in both humans and animals or pose significant environmental or agricultural impact, as well as, recombinant or synthetic nuclei acid molecules;
2) Human or non-human primate blood, plasma, serum, body fluids, unfixed tissues and cells;
3) Transgenic plants or animals; and

4) Field studies with wild animals and animal tissues inherently infected or would be experimentally infected with Biosafety Level 2 (**BSL-2**) or higher agents.

The risk of exposure to biological agents in a laboratory environment depends on several factors such as the infective agent, virulence, host's susceptibility and route of transmission.

3.4 Safety Equipment

The ZNPHL **BSL-3** laboratory shall have safety equipment including biological safety equipment, enclosed containers, safety centrifuge cups, and other engineered controls designed to minimize exposure to biological agents. Biological Safety Cabinets (BSCs) are among the most important safety equipment for protection of personnel and the laboratory environment as well as product protection. Use of appropriate ear protection equipment when working with high frequency sounds shall be employed. Safety equipment minimization of exposure is complemented by personnel training in proper use and handling of this equipment as well as regular inspection and maintenance. The laboratory manager is responsible for ensuring proper maintenance of laboratory equipment and that BSCs are certified annually by a qualified vendor.

Due to its importance in providing containment and protection in the laboratory, a BSC is considered one of the most critical pieces of safety equipment in biological laboratories. When used appropriately, BSCs are designed to contain aerosols that may be generated during work with biological materials. The BSC is equipped with a high efficiency particulate air ("HEPA") filtration that is responsible for filtering the air from the BSC before it is recirculated or exhausted.

Class II BSC is the most suitable as it protects the material being manipulated inside the cabinet from external contamination. It meets requirements to protect personnel, the environment, and the product.

The gas-tight **Class III BSC**, or glove box, provides the highest attainable level of protection to personnel, the environment, and the product. It is the only unit that provides a total physical barrier between the product and personnel. It is used with high-risk biological agents (e.g., Ebola Virus Disease) and when absolute containment of highly infectious or hazardous material is required.

There are two specialized forms of quality control that are strongly recommended for all BSCs and are required for cabinets used to contain Risk Group 2 or higher agents, these include:

3.4.1 Environmental Health & Safety

The ZNPHL management will ensure that there is a routine staff medical surveillance plan and designated regulatory authorities will ensure personnel vaccinations and medical certificates are updated as outlined in the Occupational Health and Safety Act No 36 of 2010 and other institutional requirements. The Ministry of Labour, Occupational Health and Safety Institute in conjunction with the Environmental Department in the Ministry of Health will ensure that the BSC is meeting its operating specifications and providing maximum protection to personnel and the environment as per Occupational Health and Safety Act No 36 of 2010 and the Factories Act Cap 441.The designated regulatory authorities shall ensure that installation certification and annual recertification's are completed and documentation of daily maintenance and checks of magnahelic gauge and alarm systems for the **BSL-3** laboratories are up to date. In an event where the certification lapses, the BSC shall not be used for **BSL-2** or higher procedures until it is recertified. An "OUT OF SERVICE" will be affixed on it before recertification.

3.4.2 Facility Design

Facility design is very important in providing a barrier to protect personnel working inside and outside the laboratory, including protecting people or animals in the community from infectious agents that may be accidentally released from the laboratory. Facility design must be proportionate with the laboratory's functions and the recommended biosafety level for the agent being processed or stored. The recommended standard secondary barrier(s) will depend on the risk of transmission of specific agents being handled. In **BSL-3** facilities, safeguards such as directional airflow, airlock-controlled entry and exit and a shower for personnel to shower out may be required. As the risk for aerosol generation and transmission increases, higher levels of primary containment and multiple secondary containment barriers may become necessary to prevent infectious agents from escaping into the environment. Such facility design features could include but not limited to: specialized ventilation systems to ensure directional airflow; air treatment systems for decontamination; removal of agents from exhaust air; controlled access zones; an airlock at the laboratory entrance; or separate buildings for physical isolation of the laboratory building itself.

Table 1: Description of Biosafety Levels Practices and Safety Barriers

Biosafety Level	Biological Agents	Practices	Primary Barriers and Safety Equipment	Facilities (Secondary Barriers)
1.	Not known to cause disease in healthy adults; RG1	• Standard microbiological practices	No primary barriers required. PPE: laboratory coats and gloves; eye, face protection, as needed	• Open bench top, sink required
2.	Known to cause human disease, which is rarely serious and for which preventive or therapeutic interventions are often available; RG2	• BSL-1 practice plus: • Limited access • Biohazard warning signs • Sharps precautions • Biosafety manual • Basic Microbiological Laboratory BSL-2 practices and procedures	Primary barriers: BSCs or other physical containment devices used for manipulations of agents that cause splashes or aerosols of infectious materials. PPE*:* lab coats; gloves; eye/face protection as needed.	• BSL-1 plus: • Autoclave available • Basic Microbiological Laboratory BSL-2 facility design
3.	Associated with human and animal disease for which preventive or therapeutic interventions may be available; RG3	• BSL-2 practice plus: • Controlled access • Decontamination of all waste • Decontamination of lab clothing before laundering • Baseline serum as recommended by Occupational Health • BSL-3 Biosafety Manual • BSL-3 SOPs • BSL-3 Emergency Response Plans ("ERPs") • BMBL BSL-3 practices and procedures	Primary barriers: BSCs or other physical containment devices used for all open manipulations of agents. *PPE:* protective lab clothing; gloves; face, eye and respiratory protection as needed.	• BSL-2 plus: • Physical separation from access corridors • Self-closing, double-door access • Exhausted air not recirculated • Negative airflow into laboratory • BMBL facility design and verification
4.	Agents are likely to cause serious or lethal human and animal diseases for which preventive or therapeutic interventions are not usually available; RG4	• BSL-3 practices plus: • Basic Microbiological Laboratory BSL-4 practices and procedures • BSL-4 Biosafety Manual • BSL-4 SOPs • BSL-4 ERPs	Primary barriers*:* All procedures conducted in the BSC in combination with full-body, air-supplied, positive-pressure personnel suit.	• BSL-3 plus: • BMBL BSL-4 facility

The foundations of protective practices in a laboratory lie in an individual's laboratory experience, technical knowledge, personal work habits, and attitude toward laboratory safety. Unlike administrative controls, which are behaviors dictated by regulation or laboratory policy, the term "protective behavior" is used to mean an innate part of each individual's personal approach to the laboratory environment. As such, "protective behaviors" form the first and most important line of defense against injury or exposure in the laboratory. The ZNPHL shall during and after construction, comply with requirements of the:

1) Environmental Management Act No. 12 of 2011
2) Public Health Act Cap 295 of the Laws of Zambia
3) Occupational Health and Safety Act No. 36 of 2010
4) Biosafety Act No. 10 of 2017

3.5 Basic Laboratory Practices

Cautious practices and good techniques are of primary importance in laboratory safety. They are based on comprehensive technical knowledge, experience, reasonableness, and an attitude of courteousness and thought for others. Techniques and practices are outlined in detail as "Standard Microbiological Practices" in the CDC and WHO Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition. At a minimum, the seven basic rules of biosafety, should be the basis of any personal laboratory work ethic as outlined in **table 2**:

Table 2: Biosafety Practices and Blocked Routes Exposure

Biosafety Practice	**Routes of Exposure Blocked**
1. Do not mouth pipette.	Inhalation, ingestion, skin, and mucous membrane contact
2. Manipulate infectious fluids carefully to avoid spills and the production of aerosols.	Inhalation, skin, and mucous membrane contact
3. Restrict use of sharps to those procedures for which there are no alternatives; dispose of sharps in leak- and puncture-proof containers.	Percutaneous, inhalation
4. Use laboratory coats, gloves, safety eyewear, and other personal protective equipment.	Skin and mucous membrane contact
5. Wash hands before and after all laboratory activities, following the removal of gloves, and immediately following contact with infectious agents.	Skin and mucous membrane contact
6. Decontaminate work surfaces before and after use, and immediately after spills.	Skin and mucous membrane contact
7. Do not eat, drink, store foods, or smoke in the laboratory.	Ingestion, skin, and mucous membrane contact

3.6 Laboratory Practice and Technique

Stringent adherence to standard microbiological practices and techniques is the most important constituent of containment. Personnel working with infectious agents or infected materials must be mindful of potential exposures and be trained and proficient in the practices and techniques required for safe handling of such materials. The laboratory shall be responsible for ensuring that laboratory personnel are appropriately trained.

3.7 Risk assessment

As per legal requirement, the ZNPH laboratory shall conduct a risk assessment 'suitable and sufficient' reflecting the nature of the work being assessed and develop an operational manual highlighting specific hazards that may be encountered and stipulating practices and procedures designed to minimize or eliminate risks. Laboratory personnel safety practices and techniques must be supplemented by appropriate facility design and engineering features, safety equipment, and management practices. The laboratory shall designate a person as the Laboratory Safety Coordinator.

3.7.1 Universal Precautions

Prudent practices often overlap with a set of practices known as "universal precautions." Universal precautions require that all human blood and tissues be handled as though they are infectious. Adopting and applying universal precautions to all laboratory reagents clearly creates a heightened awareness of potential risk and adds another level of caution to activities involving reagents.

3.8 Administrative Controls

Administrative controls are policies and procedures intended to assist with the safe handling of potentially hazardous biological materials. These include training, medical surveillance, vaccinations, access control, etc.

3.9 Security and Inventory of Biological Agents

The laboratory shall develop site-specific measures that will safeguard all biological materials, regardless of their risk group, from unauthorized removal. The Laboratory Manager shall ensure that the laboratory implements sufficient security measures and procedures to prevent unauthorized access to biological agents.

3.9.1 Storage and Labelling

Biological agents shall be stored using leak proof and sealed containers. Storage containers shall be clearly labelled with a unique identifier for each agent in accordance with Biosafety and biosecurity guidelines (coding) including the universal biohazard symbol as physical space on the container permits. Freezers, refrigerators, and other storage areas will also be labelled with the biohazard symbol; exceptions to this policy will be considered on an individual basis by the laboratory. Waste and contaminated equipment or other objects to be decontaminated shall equally be labelled with the biohazard symbol.

3.10 Security Plan

The ZNPHL shall ensure that there is a written security plan for each select agent that addresses at least the following topics:

- Physical security
- Cyber security
- Inventory of select agents
- Select agent transfers
- Training
- Reporting of unauthorized persons and missing materials
- Provisions for cleaning, maintenance, and repairs

3.10.1 Loss or Theft

Any case of theft or loss of select agents, the Laboratory Manager shall immediately report to the institution Security or Police and the National Biosafety Authority (NBA), which will then handle it as per NBA regulation. This plan must be available and up-to-date during an inspection.

3.10.2 Access to Select Agents

The ZNPHL will designate the right to access the facility to a few selected individuals who would have met the access criteria and security clearance. The Ministry of Justice shall approve all persons who will have access to any select agent. The approval will also require that each individual successfully passes a background security check to be independently conducted by the Zambia Police.

Unapproved persons shall only have access to select agents if escorted by an approved person. Everyone accessing a laboratory where select agents are accessible shall have security clearance

or will be accompanied by an approved person. This includes visiting scientists (on- or off-campus), maintenance workers, custodians, and vendors.

3.10.3 Incident Response Plan

The ZNPHL shall develop a written emergency plan that is laboratory specific and coordinated with the Institutional - Public Health Emergency Operational Centre (PHEOC) emergency plan. The plan shall address including the following:

- Hazards of the select agents
- Planning and coordination with emergency responders
- Building evacuation, site security, and control
- Decontamination and emergency medical treatment, and other emergency response issues

Any exposure or potential exposure shall be reported immediately and the Incident Response Plan and the Biological Spill Response Plan for the ZNPHL shall be implemented. Affected personnel shall immediately contact the Occupational Health and Safety Unit.

3.10.4 Biosafety and Record Keeping Plan

An accurate record of all select agents, from receipt to destruction or disposal, shall be maintained and will follow select agent regulations. The inventory will include specific information on individual containers and vials, as well as a record of each use, and ultimate disposal. The select agent inventory shall be verified at least monthly to account for all quantities and containers of select agents. Any discrepancies between the inventory record and the actual inventory must be reported immediately after which section 3.10.1 shall apply.

3.10.5 Personnel, Responsibilities, and Procedures for Select Agent Procurement and Receipt

(a). Training of Personnel

The ZNPHL shall ensure that all persons approved for access to select agents received documented training before beginning of work and annually thereafter. The training shall cover at least the following:

- Biosafety of select agents and their safe handling, use, and disposal

- Security requirements and procedures
- Inventory and accounting procedures
- Emergency response procedures.

The ZNPHL will maintain records of training for the work conducted by laboratory personnel or any other applicable training and will ensure designated select agent laboratories comply with select agent regulations.

(b). Training Requirements

The ZNPHL shall ensure that personnel involved in the packaging and shipping of infectious substances undergo training every two years and when regulations change. Where current training is insufficient, staff shall be obligated to receive further qualification when shipping hazardous materials of a class or division (chemical, radiological, Li-Ion Battery, etc.).

(c). Transfers of Select Agents

Select agents will only be transferred between entities that are/will be approved by the designated board to possess and use select agents. All transfers of select agents (including inter- and intra-facility transfers) shall require prior approval of the designated board.

(d). Transportation of Biological Materials

The ZNPHL Director shall appoint a Safety Manager who will ensure that packaging and transportation of biological materials is in compliant with national and international regulations. This is particularly so if the material will be transported through the "public domain," namely, those roadways, airways, and sea lanes accessible to the public.

Unless the materials are being moved within a specific campus, legal requirements governing packaging, labelling, and handling as outlined in the sample packaging and transportation SOP shall be followed (see annex 3).

3.10.6 Decontamination and Sterilization

The ZNPHL will employ both methods of inactivating biological agents, which are as follows:

(a). Decontamination

This refers to a process or treatment that renders a device, instrument, or work surface safe to handle. A decontamination procedure can range from sterilization by autoclave or ethylene oxide or simple cleaning with soap and water. Sterilization, disinfection, and antisepsis are all forms of decontamination that will be used in the laboratories.

(b). Sterilization

This is the use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores. This process includes the following:

- **Disinfection** eliminates almost all pathogenic, non-spore-forming micro-organisms but not necessarily all microbial forms on inorganic objects (work surfaces, equipment, etc.). Effectiveness is influenced by the kinds and numbers of organisms, the amount of organic matter, and the object to be disinfected and chemical exposure time, temperature, and concentration.
- **Antisepsis** is the application of a liquid antimicrobial chemical to skin or living tissue to inhibit or destroy microorganisms. It includes using germicidal solutions for swabbing an injection site on a person or animal and for handwashing. Although some chemicals may be utilized as either a disinfectant or an antiseptic, adequacy for one application does not guarantee adequacy for another. Manufacturers' recommendations for appropriate use of germicides should always be followed.

3.10.7 Methods of Decontamination

(a). General Procedures

Decontamination of cultures and objects contaminated by biological agents is routinely performed in microbiological laboratories. Decontamination is a vital component of microbiological safety practice and serves to protect laboratory personnel (as well as others) from infection and the release of infectious organisms to the outside environment (primarily through person-to-person transmission). Decontamination of media, work surfaces, and equipment is also necessary to prevent contamination of cultured organisms, including:

- Infectious wastes such as liquid and solid will be handled, treated and disposed of, according to biological waste policies and procedures.
- Liquid wastes such as bacterial or viral culture media from **BSL2** labs will be treated with appropriate disinfectant prior to sink disposal.
- Solid wastes from the **BSL2** laboratories will be segregated and placed in biohazard containers lined with biohazardous waste bags and disposed of as biological wastes. This

waste is sealed by the laboratory and shipped off-site for sterilization (see Waste Chart posted in the laboratory for more information).

- All wastes from the **BSL3** laboratories will be inactivated before disposal from the laboratory.
- A disinfectant should be chosen that is appropriate for the organism in use.
- All liquid biological cultures should be deactivated with appropriate disinfectant.
- All solid biological waste should be disposed of in the biohazard waste containers.
- Waste created in **BSL-3** laboratories is required to be autoclaved prior to removal from the laboratory.

(b). Chemical Disinfection

Disinfection is the decontamination of work surfaces, equipment, biological safety cabinets, and other inanimate objects using antimicrobial agents. Several chemical agents are used as disinfectants. Laboratory workers should remember that there are hazards associated with all these chemical disinfectants and are to be used as outlined in the chemical disinfection procedure. **Table 3** summarizes the chemical disinfectants.

(c). Biohazardous Spill Response

Even in the presence of good laboratory practice, there is a possibility of an incident or spillage involving biological materials. The priority of actions for any spillage in the ZNPHL will be determined by the "PEP" (People, Environment, and Property) rule.

The highest priority will therefore be to provide aid to injured personnel and prevent spill area access to others. This shall be done and shall be documented in the laboratory specific procedures for Biohazardous Spill Response.

Table 3: Summary of Chemical Disinfectants

Disinfectant	Use Parameters	Effective Against	Important Characteristics	Potential Application
Alcohol (ethyl, isopropyl)	*conc.*: 70-85%; *contact time*: 10-30 min.	• Vegetative cells: very positive response • Lipophilic viruses: very positive response • Tubercle bacilli: very positive response • Hydrophilic viruses: less positive response	Eye irritant, toxic, flammable, inactivated by organic matter	Surfaces: work and equipment
Chlorine Compounds	*conc.*: 0.05-0.5% (commercial bleach 0.5%); *contact time*: 10-30 min.	• Vegetative cells: very positive response • Lipophilic viruses: very positive response • Tubercle bacilli: very positive response • Hydrophilic viruses: very positive response • Bacterial spores: less positive response	May leave residue; corrosive; skin, eye and respiratory irritant; inactivated by organic matter; make up at least weekly	Spills, equipment surfaces, instruments, glassware, water baths
Quaternary Ammonium Compounds	*conc.*: 0.1-2%; *contact time*: 10-30 min.	• Vegetative cells: very positive response • Lipophilic viruses: very positive response	Toxic, inactivated by organic matter	Surfaces (work and equipment), BSCs, floor maintenance, glassware, instruments
Phenolic Compounds	*conc.*: 0.2-3%; *contact time*: 10-30 min.	• Vegetative cells: very positive response • Lipophilic viruses: very positive response • Tubercle bacilli: very positive response • Hydrophilic viruses: less positive response	Leaves residue; corrosive; skin, eye and respiratory irritant; toxic; inactivated by organic matter	Surfaces (work and equipment), BSCs, floors, spills, glassware, instruments, water baths
Iodophor Compounds	*conc.*: 0.47%; *contact time*: 10-30 min.	• Vegetative cells: very positive response • Lipophilic viruses: very positive response • Tubercle bacilli: very positive response • Hydrophilic viruses: less positive response	Leaves residue; corrosive; skin and eye irritant; toxic; inactivated by organic matter	Surfaces (work and equipment), BSCs, glassware, water baths
Formaldehyde* (Formalin)	*conc.*: 4-8%; *contact time*: 10-30 min.	• Vegetative cells: very positive response • Lipophilic viruses: very positive response • Tubercle bacilli: very positive response • Hydrophilic viruses: very positive response • Bacterial spores: less positive response	Leaves residue; skin, eye and respiratory irritant; toxic (carcinogen)	Less effective than other disinfectants but can be used for equipment surfaces, glassware, instruments **Note:** Due to its irritating characteristics and status as a carcinogen, formaldehyde should not be used without good local exhaust ventilation.
Glutaraldehyde	*conc.*: 2%; *contact time*: 10-60 min.	• Vegetative cells: very positive response • Lipophilic viruses: very positive response • Tubercle bacilli: very positive response • Hydrophilic viruses: very positive response • Bacterial spores: very positive response	Leaves residue; skin, eye and respiratory irritant; toxic	Equipment surfaces, glassware, instruments

CHAPTER 4: WASTE CARE MANAGEMENT

The ZNPHI will ensure safe management of Health-Care Waste (HCW) as a key factor in controlling and reducing nosocomial infections and promoting the protection of the surrounding environment. Laboratory Waste is part of the overall HCW management system and reflects the quality of the services provided. The ZNPHI **BSL -3** will inevitably be generating waste that may be hazardous to health as well as to the environment. Therefore, the institute will implore a structured process for monitoring, collecting, sorting, storing, transporting, and disposing of waste generated by the whole organization. Some of the waste such as sharps and pathological waste carry a higher potential for infection and injury than any other type of waste. The ZNPHL will therefore ensure that immediate segregation and appropriate disposal of sharp waste is priority. In a quest to prevent healthcare infection, the ZNPHL will adhere to proper waste management through the Zambia Environmental Management Agency Technical Guidelines on the Sound Management of Health Care Waste that all healthcare facilities adhere to through the 2011 Environmental Management Act No. 12, the Public Health Act Cap 295 of the Laws of Zambia, 2010 Occupational Health and Safety Act No. 36 and 2007 Bio Safety Act No.10. Management of waste that shall be generated by the ZNPHL shall be a responsibility of the ZNPHI.

4.1 Mandate for ZNPHI to prepare infection control and waste management plan (ICWMP) for the BSL3 lab

In the quest to control infections and manage waste, ZNPHI shall from time to time do the following:

i. Review existing documentation (Healthcare Waste Management Plans; Environment Management Plans etc.) under World Bank funded health projects;
ii. Review national policy framework related to environmental protection, waste management, pollution control, environmental health and any others relevant to the project;
iii. Detail current situation and baseline scenario of ICWM in laboratories;
iv. Define potential environment and occupational health risks related to laboratory activities, including potential chemical, physical, biological and safety hazards and routes and pathways of infections over the entire chain from collection to disposal:
    - Identify the hazards associated with an infectious agent or material.
    - Identify activities that might cause exposure to the agent or material.

v. Define the measures to be undertaken to address the risks and provide the control guidelines to be put in place to minimize the risks for exposure including:
    - SOP for waste management
    - SOP for Standard Microbiological Practices
    - Personal precautions and use of PPE
    - SOP for Occupational Health and Safety
    - Spill Management
    - Accident Response
    - Waste Management Plan.

vi. Establish a monitoring and evaluation protocol, which includes:
    - job safety analysis for procedures, tasks, or activities
    - Effectiveness of controls.

vii. Provide guidance on distribution and dissemination of awareness and information dissemination and IEC materials related to infection prevention and control and risks associated with the project activities.

viii. Define the institutional set-up, including other Ministries and agencies for monitoring, supervision, enforcement and reporting;

ix. Recommend systems for monitoring and enforcement, with the involvement of relevant environmental regulatory agencies.

x. Develop training plans to disseminate training in a phased manner using a Train-the Trainer approach and suggest feasible timeline for developing necessary training needs assessment, training modules, and roll-out of training.

xi. Estimate the budget and mobilize resources for implementation of the ICWM activities.

Critical staffing roles and responsibilities at ZNPHL will be as outlined in Annex 1

CHAPTER 5: CLASSIFICATION OF HEALTHCARE WASTE

Biohazardous waste is defined as infectious or physically dangerous medical or biological waste that because of its characteristics may cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible or incapacitating illness; or pose a substantial present potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of. The healthcare waste which will be generated in the ZNPHI laboratories include the following:

5.1 Blood and Blood Products

This will include wastes such as human or animal blood, secretions, excretions, body fluids contaminated with visible blood and materials saturated with blood.

5.2 Pathological Waste

Pathological waste will include Human tissues and body fluids removed and discarded from the procedures.

5.2.1 Cultures and Stocks of Infectious Agents and Associated Biologicals

All discarded cultures and stocks of infectious agents and associated biologicals, biotechnological by product effluents, cultures of specimens, stocks of infectious agents from the ZNPHI laboratories. This category will also include waste from the production of biologicals and discarded live and attenuated vaccines intended for human use.

5.2.2 Contaminated Animal Tissues

This will include contaminated animal tissues of all research animals known to be exposed to pathogens.

5.3 Non-risk HCW

Non-risk HCW will include all the waste that has not been infected such as general office waste, packaging, paper, non-contaminated plastic or metal, cans or glass.

5.4 Sharps

Sharps are all objects and materials that that may cause puncture or cuts and pose a potential risk of injury and infection due to their puncture or cut property. For this reason, ZNPHI will consider

sharps as one of the most hazardous waste generated in the labs and will be managed with the utmost care. Examples of such wastes include all types of needles, broken glassware, ampoules, scalpel blades and razorblades

5.5 Biotechnological by Product Effluents

This type of waste includes any discarded preparations made from the ZNPHI laboratories of genetically altered living organisms and their products. Infectious or physically dangerous medical or biological waste shall be treated as waste.

The Institute will ensure proper handling and disposal of bio-hazardous waste to prevent infection of personnel (laboratory workers, custodians, laboratory visitors, etc.) and the environment. ZNPHI shall adhere to the Environmental Management Act No. 12 of 2011 that requires proper labelling, storage and disposal of bio-hazardous waste. At a minimum, all bio-hazardous waste shall be labelled with the universal biohazard symbol and the word 'Biohazard.' Additional information, such as the type of waste (such as "sharps" or "liquid waste") and origin of the waste shall be indicated.

CHAPTER 6: HANDLING AND DISPOSAL OF BIO-HAZARDOUS WASTE

6.1 Sharps

Sharps include all syringes, lancets, scalpels, and other similar medical instruments (whether contaminated), as well as contaminated Pasteur pipettes and broken glass, and other instruments or materials that can cut or puncture personnel. ZNPHI will consider sharps as one of the most hazardous waste generated in the labs and will be managed with the utmost care. The Institute will ensure to collect all sharps in rigid containers that are leak-proof and resistant to puncture from the sharps. Sharps containers which will be used by the institute will be designed so that sharps can be safely introduced into the container but not easily retrieved.

When the sharp containers are 3/4 full, they will be sealed and picked by designated waste collector personnel. All sharps containers will be yellow in color and labelled with the universal biohazard symbol and the word 'Biohazard.' ZNPHI will adhere to WHO guidelines of infectious waste disposal.

6.2 Uncontaminated Laboratory Glassware and Broken Glass

Uncontaminated laboratory glassware and broken glass shall be collected in rigid containers (separate from other waste) that will prevent cuts and punctures to personnel. Containers will be labelled "broken glass." Broken glass will be disposed of as ordinary trash.

6.3 Solid Bio Hazardous Waste

Solid bio-hazardous waste will include microbial agents, tissue culture, and contaminated material (such as petri dishes, pipettes, contaminated glass, etc.). These materials will be collected in red biohazard bags that are double-lined.

All bioharzadous waste shall undergo autoclaving n the primary point of generation. Thereafter laboratory personnel will pack the autoclaved waste in cardboard boxes send it to the secondary industrial incinerator and shredder, as described in the ESIA. The building and room number of the source laboratory shall be written, using a permanent marker where appropriate, on the top of the box to identify its origin.

6.4 Liquid Bio-hazardous Waste

Liquid bio-hazardous waste will include all blood or liquid waste from humans or animals, and all other liquid bio-hazardous waste (such as microbial cultures). Liquid waste will be collected in a closable, rigid, plastic, leak-proof containers labelled with the universal biohazard symbol and the word 'Biohazard'.

- Human and animal blood and body fluids will be autoclaved or treated with a disinfectant prior to disposal. (Personnel handling this waste shall wear laboratory coats, safety glasses, face shield and gloves).
- Liquid waste which has been treated with small quantities of bleach or other household disinfectants will be disposed of by flushing directly to the sanitary sewer after enough contact time. Liquid waste treated with other (alcohol, for example) chemical disinfectants will be disposed of as hazardous chemical waste.
- All liquid waste disinfection events shall be documented on a log sheet.

Table 4: Color Coding and method of disposal for Various HCW Types

	Biomedical waste category	**Container colour**	**Treatment/disposal option**
1.	Human tissue waste	Yellow	Incineration/Deep burial
2.	Animal tissue waste	Yellow	Incineration/Deep burial
3.	Microbiology and biotechnology waste	Yellow	Autoclaving/Incineration/ Microwaving
4.	Sharps	Yellow	Mutilation/Autoclaving/incineration
5.	Soiled waste (items contaminated with Yellow dressings)	Yellow	Autoclaving/Microwaving/Incineration/
6.	Solid waste (for example, tubing, intravenous sets)	Yellow	Disinfection by chemical treatment/
7.	Liquid waste (from laboratory, washing	Yellow	Disinfection by chemical treatment and cleaning,
8.	Incineration ash	Black	Incineration ash landfilling Municipal
9.	Chemical waste	Yellow	Chemical treatment and discharge into drains for liquids, and secured landfills for solids
10.	General Waste	Black	Land fill
11.	Patient Waste	Yellow	Incineration/burial after treatment
12.	Culture/Specimen	Yellow	Incineration

CHAPTER 7: RECOMMENDED WASTE STORAGE, TRANSPORTATION TREATMENT AND DISPOSAL PRACTICES

7.1 Waste Storage at the BSL 3 Lab

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 healthcare wastes from the BSL3 lab:

- Initial packaging and storage would take place where healthcare waste is generated.
- Storage of waste will then be moved to a temporary on-site storage location (onsite storage refers temporary storing of disinfected solid wastes on the premises of the lab)
- Non-risk healthcare wastes would always be stored in a separate location from the infectious/ hazardous healthcare wastes 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 healthcare wastes 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 healthcare wastes before it is transferred to external storage facilities would on daily basis. External storage refers to the transit point where waste is stored after removal from primary storage to the time it is collected and transported for treatment and final disposal. External storage location would be isolated at the BSL3 lab compound.

To ensure that waste is kept separated, the central storage receptacles (include bags, bins, sharps boxes should be available to staff in each medical and other waste-producing area) for each colour coded bags will be placed in similarly colour coded receptacles.

- There will be one or more external storage points for hazardous and non-hazardous waste depending on the layout of BSL 3 laboratory.

- The external storage point(s) for the hazardous and non-hazardous waste will be geographically separate at BSL 3 laboratory section.

- The walls and floors would be smooth, without cracks, impervious, easy to clean and disinfect

- The site will be spacious, well ventilated and lit;

- All loading and unloading of waste would take place within the designated collection area around the storage point;

- Larger volume waste bins would be available at the external storage facility to receive waste containers from the internal storage points.

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

Infectious waste should be kept cool or refrigerated at a temperature preferably no higher than 3 °C to 8 °C if stored for more than a week. Unless a refrigerated storage room is available, storage times for infectious waste (e.g. the time gap between generation and treatment) should not exceed the following periods:

Temperate climate	**Warm climate**
72 hours in winter	48 hours during the cool season
48 hours in summer	24 hours during the hot season

7.2 Waste Transportation

Consideration for transportation must be based on the classification or type of waste being dealt with and the potential risk of infection to health-care workers and waste disposal staff. Transportation is classified into on-site transport and off-site transport (e.g., off-site transport

will be done for, autoclave disinfected solid waste, sludge from the onsite wastewater treatment and wastewater)**.**

7.2.1 On site transportation

The on-site transport involves conveying of wastes from the various points of generation within a laboratory to a temporary storage location also within the same area. The following would be adhered to when carrying out *On Site transportation* and every effort would be made to avoid unnecessary handling of healthcare wastes;

- 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 (external waste storage facility).
- Containers would be covered with lids during storage and transport.

7.2.2 Off-site Transportation

During the transportation of waste outside the BSL3 lab compound the following safety precautions would be needed:

- 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 the BSL3 lab, 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.

7.3 Approaches for Management of General and Health Care Solid Waste from the ZNPHI BSL3 lab

As depicted in figure 1, healthcare solid waste from the BSL-3 laboratory facility will be initially autoclaved within the laboratories as per BSL-3 biosafety requirements. From the central autoclaving system, sterilised solid waste will be shredded to reduce on the volume. The autoclaved and shredded waste will be taken to the waste collection chambers/ temporary solid waste storage facility and ultimately be transported to ZAMRA for incineration following the procedures specified in 7.2.

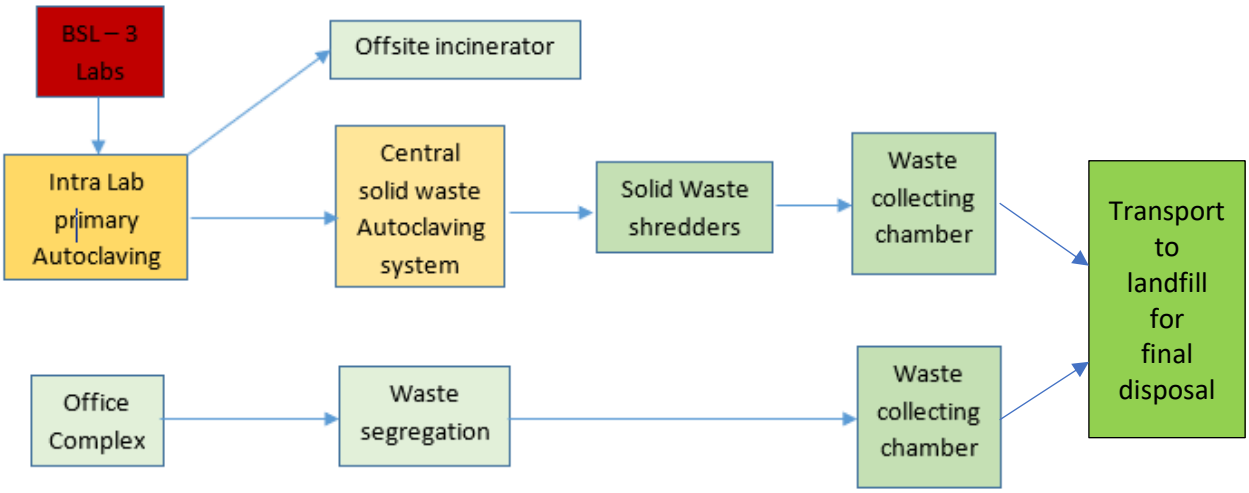

Figure 1: Management of General and Health Care Waste

7.3.1 Autoclaving

In line with the Stockholm convention on persistent organic pollutants (POPs) to which Zambia is a signatory, ZNPHI shall promote current best practices of using non- incineration methods including the use of autoclaves for health care waste management to minimize emission of POPs in order to meet the Stockholm convention requirements. Therefore, the ZNPHI shall have a central autoclaving system for sterilisation of health care solid waste. Waste from the BSL-3 laboratory will be initially autoclaved within the facility as per BSL -3 biosafety requirements provided for by WHO Laboratory Biosafety Manual. The sterilised solid waste will then be conveyed to the central solid waste autoclaving system for secondary autoclaving. The disinfected solid waste will then be transported to ZAMRA for incineration.

7.3.2 Incineration at ZAMRA

During the operational phase, ZNPHI will outsource incineration services from the ZAMRA incinerators that were commissioned in February 2018 and capable of handling medical and pharmaceutical waste. The incinerator compound is located off airport Road next to NISIR in Lusaka. Most of the incinerator materials at the site include pharmaceuticals, medicines and other materials brought for incineration. These are stored in secure storage facilities, with the highest level of hygiene. The main features of the ZAMRA incinerator are as follows:

- A minimum capacity of 50 kg/hour with high-pressure Venturi scrubbing system for air pollution control (rotary kiln design may be used for capacities above 250kg/hour).

- Double-chamber design with “controlled air” incineration principle to minimize particulate emission (with 100 percent excess air for the overall design).
- Minimum temperature of 800±50°C in the primary chamber and 1,050±50°C in the secondary chamber.
- Circular design for primary and secondary chambers (to minimize formation of air pockets observed in rectangular designs).
- A minimum of 1 sec. residence time in the secondary chamber.
- A minimum negative draft of 0.05 to 0.1 inch of water column in the primary chamber to avoid leakage of gaseous emissions from the chamber (safety precaution).
- Charging of BMW into the incinerator through a conveyor or loading device (instead of manual handling) to ensure that there is no direct exposure of the operator to the furnace atmosphere.
- Computerized programmable logic control (PLC) for the charging system to maintain specified temperatures in the primary and secondary chambers, to ensure complete combustion of the previous batch, and to avoid unsafe operating conditions.
- Emergency bypass stack.
- Graphic or computer recording devices to automatically and continuously monitor and record dates, time of day, load identification number, and operating parameters such as temperatures in both chambers, and CO and CO2 in gaseous emissions throughout the duration of the incineration cycle.
- Refractory lining of the primary and secondary chambers to sustain a minimum temperature of 1,000°C and 1,200°C, respectively.

7.3.3 Management of incinerator fly ash

Fly ash refers to dust and other finely divided particles produced during incineration. The incinerator at ZAMRA generates up to 5kg of fly ash for every 100kg of waste incinerated.

For the ZAMRA incinerator waste and effluent and by-products generated during operations are managed in the following manner: -

- Particulate emissions are trapped within the stack
- Ash (which is 5kg for every 100kg incinerated) will be transported to an approved landfill.

Disposal of fly ash from incineration, if not well managed, poses a risk for environmental (air, soil, surface water and ground water) pollution as well as health problems. This raises concerns for efficient ash disposal mechanisms.

The fly ash from the incinerator is presently collected using a dry disposal system. The incinerator is equipped with an electrostatic precipitator which removes the ash from the flue gas and maintains the flue gas emissions below 30mg/m^3. The ash is collected into ash collection hoppers and removed periodically by a pneumatic ash handling system into storage silos. During retrieval of dry fly ash from the silos, adequate water injection will be made to prevent spreading of dust.

As per the provisions of the Environmental Protection and Pollution Control Act, Ninth Schedule (Regulation 11) of the Laws of Zambia, incinerator ash can be disposed of at approved landfill sites. After collection from the storage silos, the ash will be transported by trucks and disposed off at the Chunga landfill site. Chunga landfill has an approved ESIA.

Chunga is the proposed landfill which is an engineered landfill that meets the prescribed standard. It is a licensed and accredited by Zambia Environmental Management Agency (ZEMA) which monitors operations at the site. It occupies a land area of 26 hectares and the engineered cell sits on a land area of about 5 hectares. The site was opened in 2001 followed by the engineered part which was opened in 2007.Waste received come from Municipal Solid Waste (MSW) generated in the city of Lusaka and operated by the Lusaka City Council. This means that industrial waste, waste from the trade and commerce, from institutions, markets, hospitals and clinics is collected, transported and disposed at the landfill. The landfill has a workforce of 30 workers who include the Superintendent, Foreman, Supervisors, Cashiers, Pointers and machine operators. There are different machines which include; landfill compactor, excavator, loaders, and tipper trucks (Strategic Municipal Solid Waste Management Plan for Lusaka City, 2003).

Transportation and delivery of waste is carried out by licensed transporters of waste such as Franchise contractors, Community based Enterprises and individual companies who have been given the right to collect their own waste (see table list of licensed garbage collection / solid waste management companies). Chunga landfill receives an average per day of 550 tonnes of waste per day. Zambia Environmental Management Agency (ZEMA) regulates and monitors the operations of the landfill. Paramount to the selection of a credible and operational landfill that meets the required standards is the assurance that what is planned to be dumped at these sites is

safe and does not filter into and contaminate the environment. The landfill operates under the legal provisions provided in the Environmental Management Act.

7.4 Medical Wastewater Management Approach for the proposed BSL3 lab

The complex will have two separate wastewater networks for management of healthcare waste effluent and domestic waste effluent as described below. The medical wastewater will be collected into a leak proof storage tank whose filling capacity will be auto monitored so as not to exceed ¾ full. The wastewater will then be steam sterilised using the liquid cycle of the autoclave connected to the storage tank. The autoclaved wastewater will then be discharged into the solid particle filtration system to allow solid particles to be filtered out of the waste water as it flows through the system. The filtered waste water will be collected in the retention tanks which will be vacuum tanked by licenced waste collectors for further treatment at the offsite municipal sewage treatment site (Manchinchi Wastewater Treatment Plant) at regular intervals.

The domestic waste water network will have several inspection chambers as it leads to the sedimentation tanks. A layer of accumulated solids or sludge will form at the bottom of the sedimentation tank as the waste water slowly flows through it thereby providing a level of purification prior to discharge. The sludge at the bottom of the sedimentation tanks will be periodically removed during routine maintenance as illustrated in figure 2.

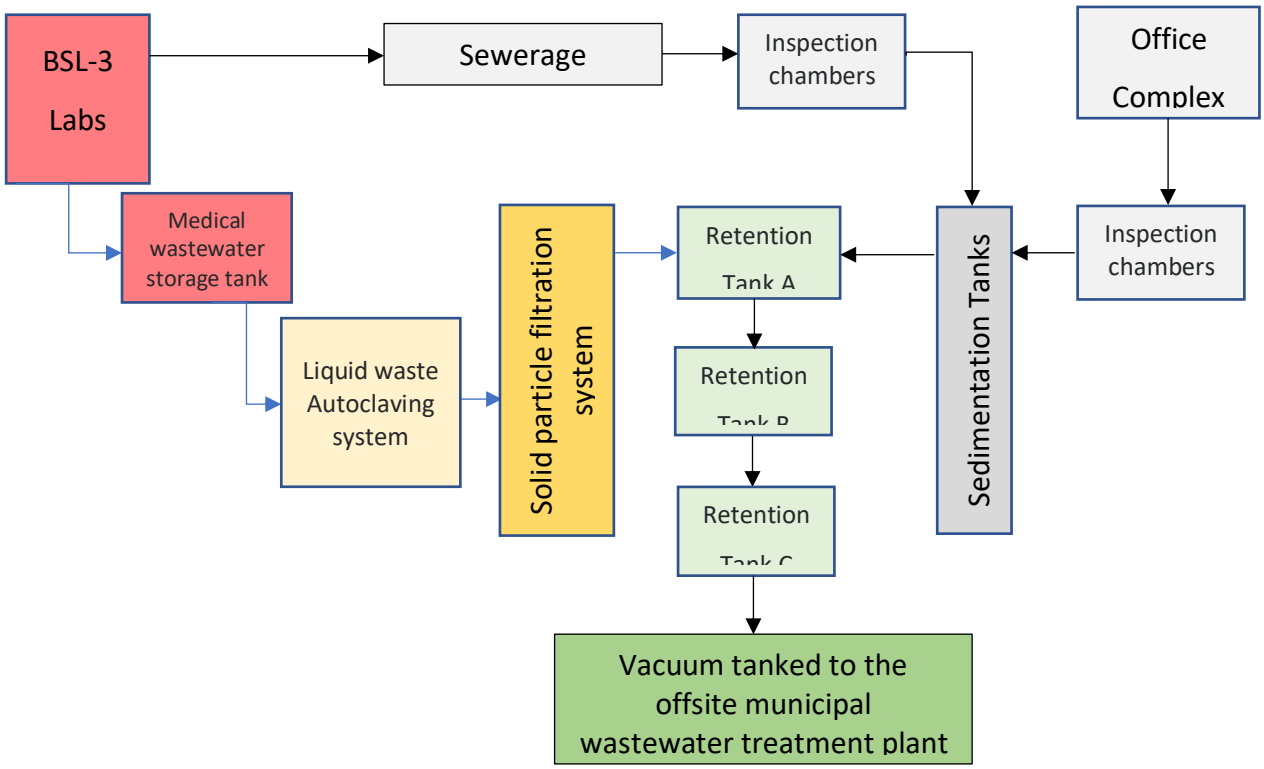

Figure 2 Management of Domestic and Laboratory Waste Water

Manchinchi Wastewater Treatment Plant

Management of wastewater in Lusaka province falls under the responsibility of the Lusaka Water and Sewerage Company (LWSC). Most wastewater in Lusaka is predominantly treated at Manchinchi Wastewater Treatment Plant (See figure 3), which has a treatment capacity of up to 36,000m3 per day, and is earmarked for upgrade to over 60,000m3 per day. Effluent is treated in accordance with Zambia Environmental Management Agency (ZEMA) stipulated standards before discharge into Ngwerere stream. The legal framework for waste water management for Zambia is contained in the Environmental Management Act (EMA), No. 12 of 2011.

Disposal of liquid waste at the plant is currently charged at the rate of K36 ($2.7) per 1,000 litres (1m3) as at 6 June 2019. The average cost of vacuum tanker services per trip is K800 ($60) and tankers available on the market have capacity ranging from 7,000 to 15,000 litres. There are around 61 private companies licensed to handle transport wastewater to Manchinchi wastewater treatment plant.

The LWSC also regulates the discharge of trade effluent into its sewer networks for both onsite and offsite sanitation using the local administration (Trade Effluent Regulations) Act of 1994. The effluent and pollution control section at LWSC monitors and regulates discharge of trade effluent and enforces the “Polluter Pays Principle” in accordance with the trade effluent regulations. The section conducts fortnight inspections on clients or operators who discharge in

its sewer networks. They also collect trade effluent samples which are analyzed for key parameters.

The plant has a section for sludge which is digested anaerobically for four months and sold as fertiliser for enriching grass, horticulture, and agriculture use. Sludge from the ZNPHI project site wastewater will be transported to Manchinchi Wastewater Treatment Plant for final disposal.

Surveillance and Maintenance of the Wastewater Treatment System

ZNPHI shall have trained Environmental Health personnel to conduct routine monitoring and surveillance of the waste management system at the complex. ZNPHI shall have trained Environmental Health personnel to conduct routine monitoring and surveillance of the waste management system at the complex. For wastewater, the officers will be responsible for collecting waste water samples, for isolation of indicator orgasms which ideally are not naturally found in the environment, at several sampling points including medical wastewater storage tank, after the wastewater autoclaving and solid particle filtration systems. In addition, ZNPHI shall have a dedicated maintenance unit that will be responsible for routine maintenance of the wastewater management system.

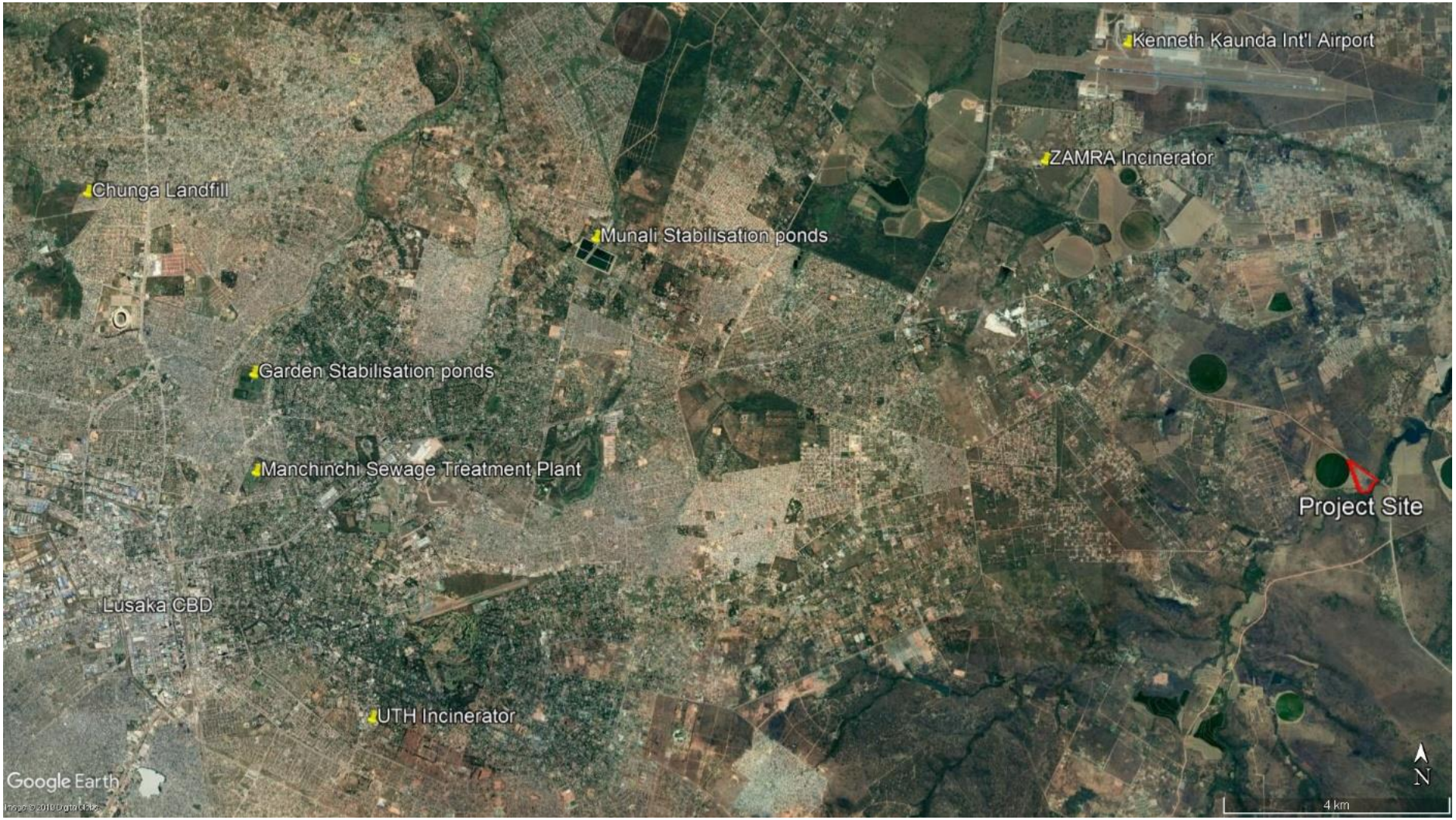

Figure 3 Locations of waste treatment systems relative to the ZNPHI Project site

CHAPTER 8: INSTITUTIONAL ARRANGEMENT FOR MONITORING IMPLEMENTATION OF THE ICWMP

For successful implementation of environmental and social risks mitigation measures, the following institutions, organizational units, committee(s) and specialists will play key roles.

8.1 ZNPHI

ZNPHI will be responsible for overall management of the proposed BSL3 lab. It will be responsible for appointing for technical and support staff required for the BSL-3 lab; capacity building; ensuring that research at the proposed BSL3 lab conforms to the best international practices (such as the NIH Guidelines, BMBL and WHO Biosafety Manual) ; 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 relevant Zambian regulatory agencies ; and facilitating the preparation of guidelines, policies and plan relevant for smooth functioning of the lab.

8.2 Project Implementation Unit (PIU)

A Project Implementation Unit (PIU) for this project will be established by Zambia National Public Health Institute (ZNPHI) which is the implementing agency. The ZNPHI Project Implementation Unit (PIU) will be responsible for ensuring compliance with the necessary, health, safety and environmental standards as specified in the ESMP and specifically during the operation phase. The ZNPHI will bear overall responsibility for environmental and social management at all the project phases. However, during the construction phase, the contractor will bear responsibility for compliance with the relevant health, safety and environmental aspects of the project.

The PIU will be required to among others undertake and assure the following during the operation phase: -

1. Review and approve the design of the BSL-3 facility and ensure that it is in line with the WHO Laboratory Biosafety Manual as appertains to design and layout.
2. Identify an independent entity to commission the facility before operations begin
3. Identify an independent entity to certify the facility before operations begin
4. Oversee the recruitment of a qualified biosafety and biosecurity officer for the BSL-3 facility

5. Oversee the establishment of a Biosafety Committee for the BSL-3 facility
6. Ensure that all the other staff recruited in the BSL-3 are competent
7. Develop or engage experts to develop Standard Operating Procedures for the BSL-3 in accordance with WHO Laboratory Biosafety Manual.

8.3 The Biosafety Committee

The Biosafety Committee will oversee the review, approval and oversight of biohazards in research activities at the EPHI campus. 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 standards and regulations. The Committee has the authority to approve, require modifications to secure approval, disapprove, suspend or terminate research activities as required to assure compliance with applicable regulations and guidelines. Besides, Biosafety Committee will monitor ICWMP implementation, supervise the Infection control and waste management system of ZNPHI 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.

8.4 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
- Advise on disinfection policy
- Prepare contingency plans for action following accidents and incidents involving biological agents
- Advise and assist management in investigations following accidents and incidents involving biological agents
- Carry out periodic inspections of containment facilities

- Develop, implement, and maintain the lab'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 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 lab'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 the Biosafety Committee on research safety procedures.
- Provide technical advice to ensure that individuals working in the wastewater treatment Plant
- Supervise the infection control and waste management system of the BSL3 lab and
- Ensure the implementation the Infection control and waste management procedure during waste handling transportation, storage, treatment and disposal
- Provide training and resources for the safe use and practices for those working with potential biohazards, and laboratory equipment.

8.5 Zambia Environment Management Authority

The Zambia Environment Management Authority (ZEMA) is responsible for ensuring environmental compliance in Zambia and its staff will further ensure that the ESMP is implemented as part of their mandate, functions and responsibilities. ZEMA will undertake surveillance on the project implementation and review compliance performance based on the supervision monitoring reports. Agreed corrective action will be undertaken by the project or its contractor within the agreed timeframe. The date of the completed action will be recorded in the log against the complainant's grievance.

Implementation of the ICWMP will be monitored to check that the mitigation measures recommended for each of the predicted impacts are implemented and effective. This will also allow for identification of any unforeseen impacts that might arise from project implementation.

ICWMP implementation monitoring will be undertaken by the ZNPHI's Environmental Health Officers and Laboratory Systems and Networks, in conjunction with the Zambia Environmental Management Agency (ZEMA) that is mandated to safeguard the environment in accordance with the 2011 Environmental Management Act (EMA) N0. 12 and 2013 Environmental Management (Licensing) Regulations, which addresses waste water management, waste management, pesticides and toxic substances as well as ozone depletion substances.

Monitoring the implementation of the ICWMP shall be monthly throughout the operation phase and reports shall be compiled by the ZNPHL Biosafety and Biosecurity Manager and shared with relevant stakeholders. Both Internal and external audits shall be conducted annually.

Monitoring will provide information for periodic review and alteration of the ESMP as may be necessary to ensure optimization of environmental protection throughout the lifespan of the project. This will ensure early detection and remediation of undesirable impacts. With respect to the envisaged activities, the environs of interest are air, land, flora, surface and ground water resources, traffic, health and safety. Each of these environs will be impacted upon as already explained in the impacts section. The monitoring plan highlights measures put in place to ensure adherence to the proposed management plan.

The main objectives of the environmental monitoring are:

1. To provide a database from which the environmental impacts of the project can be assed
2. To provide an early indication should any of the environmental control measures or practices fail to achieve the acceptable standards
3. To monitor the performance of the project and effectiveness of the mitigation measures
4. To determine project compliance with regulatory requirements, standards and government policies.
5. To take remedial actions if unexpected problems or unacceptable impacts arise.

The table below summarizes the potential negative effects and the measures the Institute plans to employ to prevent and or reduce their impact on the environment and human life, with a well-coordinated monitoring and mitigation systems and the envisioned timeframes and responsible parties.

Environmental and Social Monitoring Plan				
Environmental and Social Component	**Performance Indicators**	**Monitoring Requirements**	**Frequency**	**Responsibility**
Solid and liquid Waste	□ Scattered litter □ Signs of obstruction of water ways. □ Flow of wastewater on the ground surface. □ Provision of sanitary facilities to the construction crews.	□ Physical inspection □ Number of complaints	□ Monthly	□ Contractor
Noise Pollution	□ Level of noise generated. □ Provision of PPE. □ Compliance with existing noise standard issued by ZEMA.	□ Liaise with other stakeholders. □ Documentation on complaints about noise	□ Monthly	□ Contractor
Air Pollution	□ Level of dust generated. □ Provision of PPE.	□ Physical inspection □ Interview residents including workers □ Liaise with other stakeholders	□ Monthly	□ Contractor
Flora and Fauna	□ Amount of vegetation removed □ Change in animal behavioural patterns	□ Documentation of uprooted trees □ Observation	□ Quarterly	□ Contractor
Gender Empowerment	□ Number of female employees □ Number of male and female toilets	□ Review of company staff records. □ Physical Inspection	□ Quarterly	□ Contractor
Child Labour	□ Record of employees including IDs	□ Review of records □ Interviews with staff and local community	□ Monthly	□ Contractor
Gender Equity and Sexual Harassment	□ Number of complaints	□ Review of grievance redress forms. □ Interviews with local community	□ Monthly	□ Contractor
Loss of Life, Injury and Damage to Private property	□ Record of accidents and damages done	□ Review of records □ Interviews with staff and local community.	□ Monthly	□ Contractor
HIV&AIDS	□ Number campaign meetings on transmission of diseases like HIV/AIDS and other STDs. □ Number of condom dispensers within the site.	□ Inspection of HIV/AIDS prevention services within the site. □ Number of condoms, A provided.	□ Quarterly	□ Contractor

Environmental and Social Component	Performance Indicators	Monitoring Requirements	Frequency of monitoring	Responsibility
Design of BSL-3 Facility	□ Availability of detailed design for BSL-3 Facility in accordance with WHO Laboratory Biosafety Manual.	□ Availability of approved Detailed Design for BSL-3 Facility	□ Once during design stage	ZNHIP
Commissioning of BSL-3 Facility	□ Recruitment of consultant to undertake commissioning of BSL-3 Facility in accordance with WHO Laboratory Biosafety Manual.	□ Availability of Contract Documents showing recruitment of commissioning consultant.	□ Once during commissioning	ZNHIP
Certification of BSL-3 Facility	□ Recruitment of consultant to undertake certification of BSL-3 Facility in accordance with WHO Laboratory Biosafety Manual.	□ Availability of Contract Documents showing recruitment of certification consultant.	□ Annual or whenever changes are made in the facility e.g. fitting of new HVACs, BSC etc.	ZNHIP
Workers Exposure to Chemicals	□ Availability and proposer use of PPE for all workers □ Availability of specimen reception area □ Availability of Biosafety Cabinet □ Record of trainings given to workers on exposure minimisation □ Number of worker exposures recorded	□ Physical and routine inspections to determine use of PPEs and other equipment. □ Documentation of training given to workers □ Documentation of exposure incidences	□ Daily inspection □ Training frequency conducted annually or as needed	ZNHIP
Solid Waste (Infectious and non-infectious)	□ Availability of a functional autoclave □ Availability of a functional incinerator □ Record of trainings given to waste equipment operators	□ Physical routne inspections to ascertain use of waste disposal equipment □ Documentation of training given to workers □ Documentation of exposure incidences	□ Daily inspection □ Training frequency conducted annually or as needed	ZNHIP
Effluent Waste (Infectious and non-infectious)	□ Availability of a functional autoclave □ Record of trainings given to waste equipment operators	□ Physical routne inspections to ascertain use of waste disposal equipment □ Documentation of training given to workers □ Documentation of exposure incidences	□ Daily inspection □ Training frequency conducted annually or as needed	ZNHIP

Emergency Hazards (Fire, Electric, Noise, Radiation) etc	□ Evidence of written Contigency Plan □ Number of emergency hazards recorded □ Record of trainings given to workers on emergency response □ Presence of First-aid kit, including universal and special antidotes □ Presence of fire extinguishers, fire blankets □ Availability of Full protective clothing (one-piece coveralls, gloves and head covering, Full-face respirators with appropriate chemical and particulate filter canisters □ Availability of room disinfection apparatus, e.g. sprays and formaldehyde vaporizers □ Hazard area demarcation equipment and notices □ Evidence of fire warnings, instructions and escape routes should be displayed prominently in each room and in corridors and hallways □ Number of emergency response drills undertaken	□ Documentation of training given to workers on emergency response procedures □ Documentation of exposure incidences due to emergency hazards □ Physical and routine inspections to ascertain use of PPEs □ Physical and routine inspections to ascertain presence of emergency response equipmemt □ Documentation of emergency drills conducted □ Medical reports of noise exposure impacts on workers □ Medical reports of radiation exposure impacts on workers □ Accurate records of use and disposal of radioactive materials.	□ Daily inspection on PPE use □ Training frequency conducted annually or as needed □ Emergency drills to be conducted annually □ Regualr (semi-annual) imspection of equipment (electrical and fire) including testing tested □ Noise measurement surveys conducted annually □ Medical monitoring of worker exposure to noise undertaken annually □ Medical monitoring of worker exposure to radiation undertaken annually	ZNHIP
Bio-Security Hazards	□ Availability of Bio-Security Protocol □ Number of Bio-security related breaches □ Record of trainings given to workers on biosecurity	□ Documentation of training given to workers on biosecurity □ Documentation of exposure incidences due to biosecurity breaches	□ Biosecurity protocol review to be undertaken annually □ Quarterly inspections on all the aspects in the facility aimed at ensuring security enhancement	ZNHIP
Personnel Training and Capacity Enhancement	□ Availability of organisational training program on safety □ Record of trainings given to workers on BSL-3 safety measures □ Availability of Biosafety Officer □ Availability of Biosafety Committee	□ Documentation of training given to workers on safety □ Documentation of number of meetings held by Biosafety Committee (minutes of meeting) □ Availability of contract for Biosafety Officer	□ Training frequency conducted annually or as needed □ Biosafety Committee meetings to be held on a monthly basis	ZNHIP

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ANNEX 1: ZAMBIA NATIONAL PUBLIC HEALTH LABORATORY STAFFING AND RESPONSIBILITIES

ZNPHI BSL 3 Laboratory Staffing

The proposed BSL3 lab will require both professional and auxiliary staff for the continuous and proper operation of the facility. The Zambia National Public Health BSL-3 facility will employ the following staff on full-time bases and with an exception of Laboratory Director and the Laboratory Quality and Safety Managers; the number of personnel will be determined by the laboratory's work load.

- Laboratory Director
- Technical Staff
    - Laboratory scientist
    - Laboratory Quality Manager
    - Biosafety and Biosecurity Manager
    - Occupational and Safety Manager
- Maintenance staff
    - Engineers
- Support Staff
    - Cleaners
    - Security staff

Roles and Responsibilities

The ZNPHI will establish a strong biosafety and biosecurity department which will address biosafety and biosecurity and ensure compliance with regulations and recommendations in accordance with Occupational health and Safety Act No 36 of 2010, Biosafety Act No. 10 of 2017 and Environmental Management Act No. 12 of 2011. Outlined below are the roles and responsibilities of the staff responsible for the biosafety and biosecurity at the ZNPHI.

Zambia National Public Health Laboratory (ZNPHL) Director

The ZNPHL Director will be responsible for the overall management of the proposed BSL3 facility. To ensure compliance to biosafety and biosecurity, ZNPHI will be responsible for:

- Appointing a laboratory director, biosafety and biosecurity Manager and any other technical and support staff as will be required for the BSL-3 laboratory.
- Appropriate personnel training in handling and manipulation of potentially infectious materials.
- Establishing and sustaining a *Biosafety Committee*

- Ensuring that all research conforms to the provisions of best national and international practices as stipulated in the National Health Research Authority (NHRA) guidelines.
- Establishing and maintaining a health surveillance program for laboratory personnel.
- Reporting, when required, any significant problems, violations or significant research-related accidents or illnesses to the Occupational Health and safety Institute.
- Facilitating for the preparation of the relevant policies, procedures, guidelines, and plans for smooth functioning of the BSL3 laboratory.

ZNPHI BSL3 Laboratory Biosafety and Biosecurity Committee

The Biosafety Committee will advise, review and approve policies and procedures related to procurement, use, storage, transportation, and disposal of biohazardous materials. The committee will also review, approve, and oversee research involving recombinant/synthetic DNA/RNA and also other biohazardous agents at the BSL3 laboratory.

The committee will also take up the responsibility of facilitating assessments in collaboration with the National Biosafety Authority (NBA) as well as development of procedures, and training of research personnel and ensuring compliance with the Biosafety Act N0 10 of 2017. The Committee will have 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. Membership will consist of experts in biomedical research practices and biosafety and biosecurity with at least two members representing the interest of the surrounding community with respect to health and protection of the environment (these will either be state officials, environmental protection agencies, or persons active in medical, occupational health or environmental concerns in the community). The mentioned representatives of the communities' interest will be officially appointed by the ZNPHI board of Directors.

BSL 3 Laboratory Director

The ZNPHI will appoint a scientist, knowledgeable in laboratory techniques, processes and procedures as well as laboratory Quality Management Systems as a laboratory director with the following responsibilities.

- Coordinate performance and documentation of laboratory risk assessment for the biological agent(s)
- Comply with national and international guidelines on handling and transportation of infectious substances including documentation for international, interstate and intrastate transport of genetically modified and biohazardous material.
- Ensure that all appropriate personal protective equipment (PPE) is proved by ZNPHI management and used by all laboratory staff as well as adequate training in laboratory techniques, biosafety and biosecurity and quality management systems.
- 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 or select agents
- Define quality policy objectives and management responsibilities relevant to the organizational goal.
- Planning, developing and allocation of appropriate resources to the medical environment and provide educational programmes for the medical and laboratory staff.
- Ensure that personnel have sound knowledge and recognize the importance of participatory approach in policies and goals of the Quality Management System as well as needs of clients, laws and regulations.
- Approve and provide leadership and direction on the utilization of the quality manual, standard operating procedures, work instructions and regulations of the ZNPHL.
- Ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory;
- Ensures the completeness of the Quality Management System (QMS) and its continued maintenance and review.
- Relates and functions effectively with regulatory agencies and the healthcare community and the client population being saved.
- Propose appropriate microbiological practices and laboratory techniques to be used for the research.
- Immediately report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biosafety Committee
- Ensuring that individuals working in the facility are experienced and proficient in handling the biological agents at the appropriate level of containment

- Monitor and authorize access of all persons entering the BSL-3 laboratory.
- Conduct performance appraisal of laboratory staff.

Laboratory Scientists

The responsibilities of the Laboratory Scientist will include but not limited to:

- Performing microbiological, molecular and any other required tests as outlined in the ZNPHL hand book and as assigned by the Laboratory director
- Maintaining knowledge on various testing methods and perform all manual and automated operations on various supplies.
- Developing and preparing necessary Standard Operating Procedures (SOPs)
- Performs laboratory analysis and maintain records as defined by the ZNPHL laboratory Quality Management System
- Assisting, initiating and guiding junior researchers in adoption and adaptation of new and emerging laboratory methods and technologies

Laboratory Quality Manager

The responsibilities of the Laboratory quality officer

- Development, update, revision and maintenance of the Quality Management System, Quality Manual, Standard Operating procedures, and other quality documents.
- Coordinate performance and documentation of corrective action and preventive action, including follow-up monitoring of the effectiveness of the corrective action.
- Planning and carrying out internal audits of the Quality Management System.
- Ensure the completeness of the Quality Management System (QMS) and its continued maintenance and review.
- Planning, conducting and facilitating quality assurance training workshops and seminars.
- Monitor performing all Quality Assurance /Quality Control procedures for analytical tests
- Maintain current and updated demonstrations of capability for all test procedures in the laboratory for which quality assurance oversight will be performed.

- Ensure the fulfilment of the compliance by the laboratory technical staff as well as maintenance and supportive staff with relevant regulations, guidelines, and policies of infection control and waste management.

- Compilation and distribution of performance reports for Management review.
- Select and monitor all network laboratories for quality of service;
- Identification and addressing of complaints, non-conformances and corrective actions.
- Interact with the accreditation bodies on behalf of the organization

Biosafety and Biosecurity Manager

The responsibilities of the Biosafety and biosecurity Manager

- Ensure proper containment and compliance with handling of infectious materials
- Develop and maintain the BSL3 Biosafety Manual in collaboration with the Biosafety and Biosecurity Manager and other subject matter experts
- Develop detailed specific biosafety Standard Operating Procedures (SOPs) for biohazards used in the laboratory.
- Develop and conduct biosafety and biosecurity training for scientists, researchers and support staff working in the laboratory.
- Conduct biosafety and biosecurity drills and simulations.
- Provide technical advice to laboratory director and the Biosafety Committee on research safety procedures.
- Coordinate development, implementation, and maintenance of ZNPHL biosafety and biosecurity program.
- Monitors laboratory incidents and reports to management.

Environmental Health Manager

- Ensures safe and appropriate disposal of laboratory waste.
- Adhering to infection prevention and control and waste management procedures during handling of infectious materials

- Responsible for the health and safety of all laboratory staff working with Infectious/potentially infectious materials
- Supervises Compilation of a list of all hazardous materials, chemicals and reagents used in the ZNPH-Laboratory, followed by Material Safety and Data Sheets (MSDS) for each hazardous substance.
- Coordinate perform and review of laboratory risk assessment to determine appropriate biosafety level and personal protective equipment (PPE) for handling infectious and recombinant materials.
- Ensure adequate training and compliance by laboratory personnel with relevant regulations, guidelines, and policies.
- Ensure that all appropriate personal protective equipment (PPE) is provided by ZNPHI management and used by all laboratory staff
- Relate and function effectively with environmental, occupational health hazards and fire regulatory agencies.
- Supervise waste collectors, laboratory cleaners and maintenance unit

Support Staff

The facility will further require a number of auxiliary staff to facilitate for the security, upkeep and cleanliness of the Laboratory. These include;

Security Staff

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

Waste Handlers

- Collect, segregate, contain, label and transport solid waste, medical waste & recyclable goods from generation points to specified collection sites.
- Monitor available waste receptacle capacity; alerting supervisor to ensure that the unit is emptied before reaching full capacity.
- Clean and disinfect medical waste carts and totes. Maintain waste area facility in a clean and orderly condition, including at the end of each shift.

- Operate in compliance with the waste management procedure during waste handling transportation, storage, treatment and disposal including infection control.

Laboratory Cleaners

Their responsibilities will mostly comprise of activities aimed at maintaining laboratory equipment and the outside surroundings of the BSL-3laboratory and these will include;

- Cleaning laboratory equipment, such as glassware, metal instrument etc. as well as sterilization of glassware and instruments.
- Preparation of cleaning solution according with manufacturer's specifications and laboratory SOPs.
- Scrubbing walls, floors, shelves, tables, and sinks, using appropriate cleaning utensils and cleaning bases.
- 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.

ANNEX 2: OTHER HEALTH AND SAFETY RECOMMENDATIONS

The following shall apply to all

1. Ensure that construction workers are provided with adequate supply of wholesome drinking water which should be maintained at suitable and accessible points.

2. Ensure that conveniently accessible, clean, orderly, adequate and suitable washing facilities are provided and maintained within the site.

3. Ensure all wastes or debris arising from any demolitions are transported to licensed site for disposal. Costs to be included in contractual agreements of contractors

4. Provide facilities for proper handling and storage of construction materials.

5. Encourage reuse packaging materials such as cartons, cement bags, empty metal and plastic containers to reduce waste at the site

6. Ensure all wastes are segregated, collected and stored in appropriate containers and removed from site at agreed times. The wastes shall be segregated into those for recycling, hazardous waste, and wastes for disposal with general household waste. Only register carriers will be used to remove wastes from the site, and the removed wastes shall be taken to the nearest appropriate facility that is registered to receive that type of waste. Costs to be included in contractual agreements of contractors.

7. Sprinkle water on graded access routes as necessary to reduce dust generation by construction works and vehicles. Costs to be included in contractual agreements of contractors.

8. Sensitize truck drivers to avoid unnecessary racing of vehicle engines at loading/offloading points and parking areas. Switch off vehicle engines when not needed.

9. Sensitize construction drivers to avoid gunning of vehicle engines or hooting especially as these works will be done at health facility

10. Ensure that construction machinery are kept in good condition to reduce noise generation.

11. Provisions must be put in place for the formation of a Health and Safety Committee, in which the employer and the workers are represented.

12. The contractor to ensure suitable, efficient, clean, well-lit and adequate gender specific sanitary conveniences are provided for construction workers.

13. Ensure that machinery, equipment, personal protective equipment, appliances and hand tools used in construction do comply with the prescribed safety and health standards and be appropriately installed maintained and safeguarded.

14. Ensure that materials (cement bags, aggregates, bitumen drums) are stored or stacked in such manner as to ensure their stability and prevent any fall or collapse

15. Orient the public on risks related to construction sites. Costs to be included in contractual agreements of contractors

16. Ensure that items are not stored/stacked against weak walls and partitions

17. All floors, steps, stairs and passages of the premises must be of sound construction and properly maintained

18. Design suitable documented emergency preparedness and evacuation procedures to be used during any emergency. Such procedures must be tested at regular intervals

19. Ensure that adequate provisions are in place to immediately stop any operations where there in an imminent and serious danger to health and safety and to evacuate workers

20. Fire-fighting equipment should be provided at strategic locations such as stores and construction areas.

21. Signs such as **"NO SMOKING"** must be prominently displayed within the premises, especially in parts where inflammable materials are stored

22. To provide adequate both natural and artificial ventilation

23. The contractor to provide a well-stocked first aid box which is easily available and accessible should be provided within the premises

24. Ensure that all chemicals used in construction are appropriately labelled.

25. Keep a record of all hazardous chemicals used at the premises, cross-referenced to the appropriate chemical safety data sheets

26. There should be no eating or drinking in areas where chemicals are stored or used and should only be in defined areas

27. Ensure that workers at the excavation sites and other dusty sites are adequately protected from inhalation of substantial quantities of dust through provision of suitable protective gear (e.g. nose masks)

28. Ensure suitable overalls, safety footwear, dust masks, gas masks, respirators, gloves, ear protection equipment are made available and construction personnel are trained to use the equipment

29. Provide workers in areas with elevated noise and vibration levels, with suitable ear protection equipment such as ear muffs

30. All work places must be kept in a clean state, and free from effluvia arising from any drain, sanitary convenience or nuisance

31. Ensure the general safety and security at all times by providing day and night security guards and adequate lighting within and around the Construction site.

32. Awareness creation and sensitization to workers and other persons engaged in the project to eliminate chances of infections of HIV-AIDS and other sexually transmitted diseases.

33. Restriction to the construction site

ANNEX 3: PROTOCOL FOR TRANSPORTATION OF INFECTIOUS SUBSTANCES

Introduction

Human and animal specimens are collected and shipped within countries and across international borders for a variety of reasons, including disease investigations, clinical trials, surveillance studies, antidoping testing, routine analyses, etc. The protocol provides information for;

- classifying infectious substances for transportation and ensuring their safe packaging.
- facilitating 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 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 also emphasizes on 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. It is adopted from WHO Guidance on regulations for the transport of infectious substances 2015–2016.

Classification

Dangerous goods are assigned UN numbers and proper shipping names according to their hazard classification and their composition. Proper shipping names are used to clearly identify the dangerous article or substance.

Infectious substances are classified in Division 6.2 and assigned to UN 2814, UN 2900, UN 3291 or UN 3373, as appropriate.

Infectious substances are divided into the following categories:

Category A

An infectious substance 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.

Note: An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.

a) Infectious substances meeting these criteria which cause disease in humans or both in humans and animals shall be assigned to United Nations number UN 2814. Infectious substances which cause disease only in animals shall be assigned to UN 2900.
b) Assignment to UN 2814 or UN 2900 shall be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

Note 1: The proper shipping name for UN 2814 is INFECTIOUS SUBSTANCE, AFFECTING HUMANS. The proper shipping name for UN 2900 is INFECTIOUS SUBSTANCE, AFFECTING ANIMALS only

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.

Note: The proper shipping name of UN 3373 is "BIOLOGICAL SUBSTANCE, CATEGORY B"

Exemptions

Substances that do not contain infectious substances or that are unlikely to cause disease in humans or animals are not subject to dangerous goods regulations, unless they meet the criteria for inclusion in another class.

Substances containing microorganisms which are non-pathogenic to humans or animals are not subject to dangerous goods regulations, unless they meet the criteria for inclusion in another class. Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subject to dangerous goods regulations, unless they meet the criteria for inclusion in another class.

Note: Medical equipment which has been drained of free liquid is deemed to meet the requirements of this paragraph and is not subject to dangerous goods regulations.

Environmental samples (including food and water samples) which are not considered to pose a significant risk of infection are not subject to dangerous goods regulations, unless they meet the criteria for inclusion in another class.

- Dried blood spots, collected by applying a drop of blood onto absorbent material are not subject to dangerous goods regulations. Faecal occult blood screening samples are not subject to dangerous goods regulations.
- Blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation as well as samples drawn in connection with such purposes are not subject to dangerous goods regulations.
- Human or animal specimens (patient specimens) for which there is minimal likelihood that pathogens are present are not subject to dangerous goods regulations if the specimen is transported in a packaging which will prevent any leakage and which is marked with the words "Exempt human specimen" or "Exempt animal specimen", as appropriate. The packaging should meet the following conditions:
  a) The packaging should consist of three components:
     i) a leak-proof primary receptacle(s);
     ii) a leak-proof secondary packaging; and
     iii) an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm × 100 mm;
  b) For liquids, absorbent material in sufficient quantity to absorb the entire contents should be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material;
  c) When multiple fragile primary receptacles are placed in a single secondary packaging they should be either individually wrapped or separated to prevent contact between them.

Note 1: An element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. Examples of specimens which may be transported under this paragraph include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antigen (PSA); those required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring; those conducted for insurance or employment purposes and are intended to determine the

presence of drugs or alcohol; pregnancy test; biopsies to detect cancer; and antibody detection in humans or animals in the absence of any concern for infection (e.g. evaluation of vaccine induced immunity, diagnosis of autoimmune disease, etc.).

Note 2: For air transport, packagings for specimens exempted under this paragraph shall meet the conditions in (a) to (c).

Except for:

a) Medical waste (UN 3291);
b) Medical devices or equipment contaminated with or containing infectious substances in Category A (UN 2814 or UN 2900); and
c) Medical devices or equipment contaminated with or containing other dangerous goods that meet the definition of another hazard class, medical devices or equipment potentially contaminated with or containing infectious substances which are being transported for disinfection, cleaning, sterilization, repair, or equipment evaluation are not subject to the provisions of dangerous goods regulations if packed in packagings designed and constructed in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents. Packagings shall be designed to meet specific construction requirements – this is not considered further in these guidelines.

These packagings shall meet general packaging requirements not considered further in these guidelines, and be capable of retaining the medical devices and equipment when dropped from a height of 1.2 m. For air transport, additional requirements may apply.

The packaging shall be marked "USED MEDICAL DEVICE" or "USED MEDICAL EQUIPMENT". When using overpacks, these shall be marked in the same way, except when the inscription remains visible.

Biological products

For the purposes of transport, biological products are divided into two groups:

a) those which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals. Substances in this group are not subject to dangerous goods regulations;

b) those which do not fall under paragraph (a) and are known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B. Substances in this group shall be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

Note: Some licensed biological products may present a biohazard only in certain parts of the world. In that case, competent authorities may require these biological products to be in compliance with local requirements for infectious substances or may impose other restrictions.

Genetically modified microorganisms and organisms

GMMOs or GMOs that do not meet the definition of toxic substances or infectious substances shall be assigned to UN 3245. GMMOs and GMOs assigned to UN 3245 shall be shipped following Packing Instruction P904 (ICAO/IATA PI959) – this is not considered further in these guidelines.

Note: The proper shipping name for UN 3245 is “GENETICALLY MODIFIED MICROORGANISMS” or "GENETICALLY MODIFIED ORGANISMS".

Medical or clinical wastes

Medical or clinical wastes containing Category A infectious substances shall be assigned to UN 2814 or UN 2900 as appropriate. Medical or clinical wastes containing infectious substances in Category B, or which are reasonably believed to have a low probability of containing infectious substances, shall be assigned to UN 3291 and shipped following Packing Instruction P621 (ICAO/IATA PI622) – this is not considered further in these guidelines. For the assignment, international, regional or national waste catalogues may be taken into account.

NOTE: The proper shipping name for UN 3291 is “CLINICAL WASTE, UNSPECIFIED, N.O.S.” or "(BIO) MEDICAL WASTE, N.O.S." or "REGULATED MEDICAL WASTE, N.O.S.".

Decontaminated medical or clinical wastes which previously contained infectious substances are not subject to dangerous goods regulations unless they meet the criteria for inclusion in another class.

The bulk transport of wastes of Division 6.2 (UN 3291) is permitted according to provisions not further considered in these guidelines.

Infected animals

Unless an infectious substance cannot be consigned by any other means, live animals shall not be used to consign such a substance. A live animal which has been intentionally infected and is known or suspected to contain an infectious substance shall only be transported under terms and conditions approved by the competent authority.

Animal material affected by pathogens of Category A or which could be assigned to Category A in cultures only, shall be assigned to UN 2814 or UN 2900 as appropriate. Animal material affected by pathogens of Category B other than those which would be assigned to Category A if they were in cultures shall be assigned to UN 3373.

The bulk transport of animal material containing infectious substances (UN 2814, 2900 and 3373) is authorized according to provisions not further considered in these guidelines.

General preparation of shipments for transport

Due to the different 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. 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. Carriers and forwarding agents shall supply details of local suppliers or local companies that can provide such information.

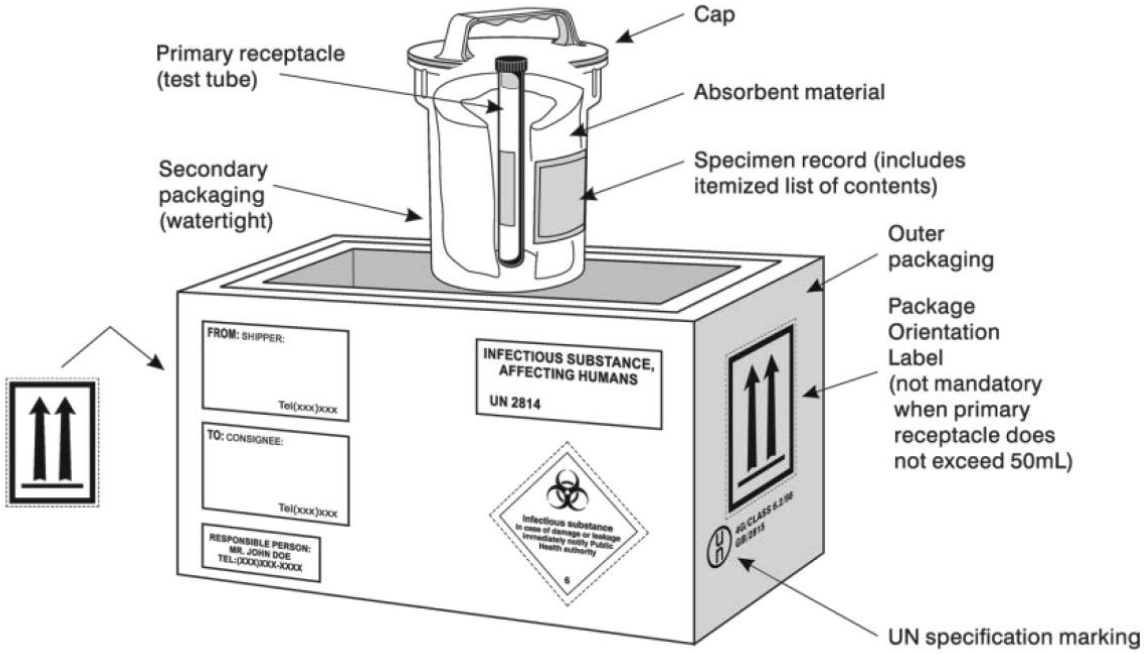


Figure A1. Example of triple packaging system for the packaging and labelling of Category A infectious substances

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 A2. 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

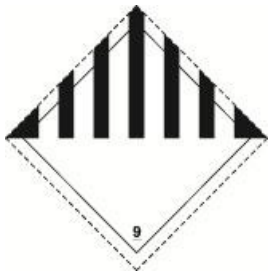
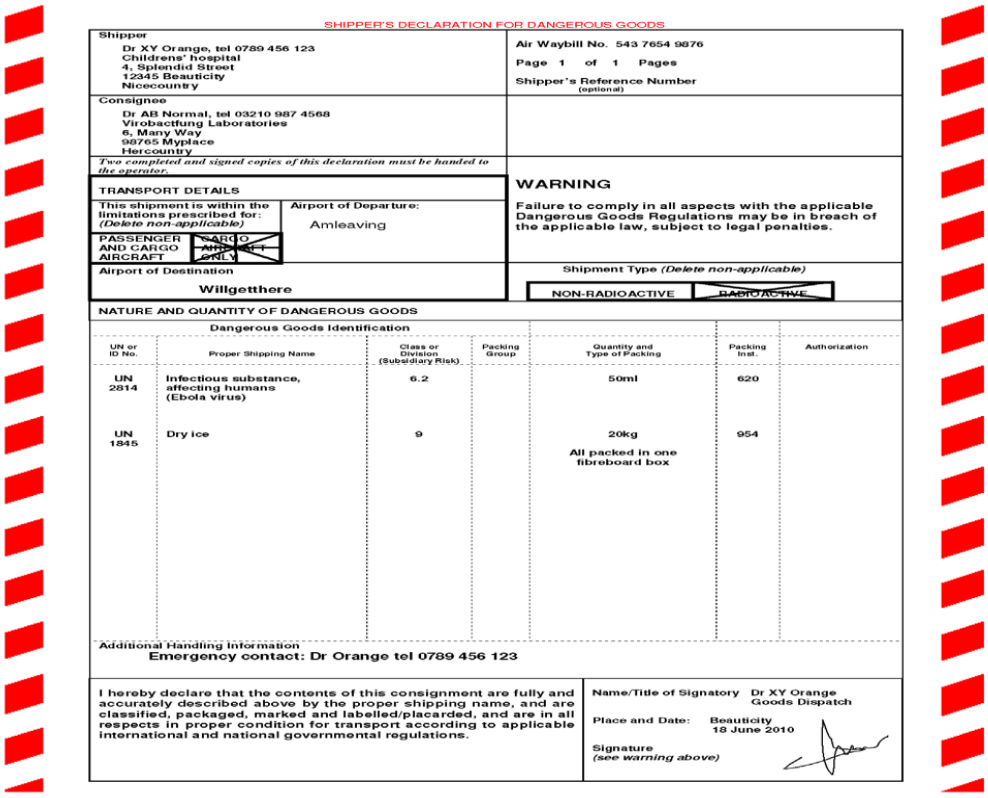


Figure A3 . Hazard label for certain noninfectious genetically modified microorganisms and organisms (UN 3245) and for carbon dioxide, solid (dry ice) (UN 1845); substances packed in dry ice (see section on Refrigerants) shall bear this label in addition to the primary risk label (e.g. the label shown in

Shipping empty packaging'

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



SHIPPER'S DECLARATION FOR DANGEROUS GOODS

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

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

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

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

TRANSPORT DETAILS

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

Airport of Departure: Amleaving

Airport of Destination: Willgetthere

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

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

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification

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

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

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

Name/Title of Signatory Dr XY Orange
Goods Dispatch

Place and Date: Beauticity
18 June 2010

Signature
(see warning above)

Figure A4. Example of a completed shipper's Declaration for Dangerous Goods

Documentation

The following shipping documents are required.

To be prepared and signed by the shipper:

- for air: the shipper's Declaration for Dangerous Goods
- a packing list/proforma invoice that includes the receiver's address, the number of packages, detail of contents, weight, value (Note: for international transport, a minimal value shall be indicated, for customs purposes, 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 shipments.

For UN 2814 and UN 2900, an itemized list of contents shall be enclosed between the secondary packaging and the outer packaging.

For the purposes of documentation, the proper shipping name shall be supplemented with the technical name. Technical names need not be shown on the package. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in category A and assignment to UN 2814 or UN 2900, the words "suspected Category A infectious substance" shall be shown, in parentheses, following the proper shipping name on the transport document, but not on the outer packagings.

Packaging, labelling and documentation requirements for infectious substances in

Category B Packaging

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.

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.

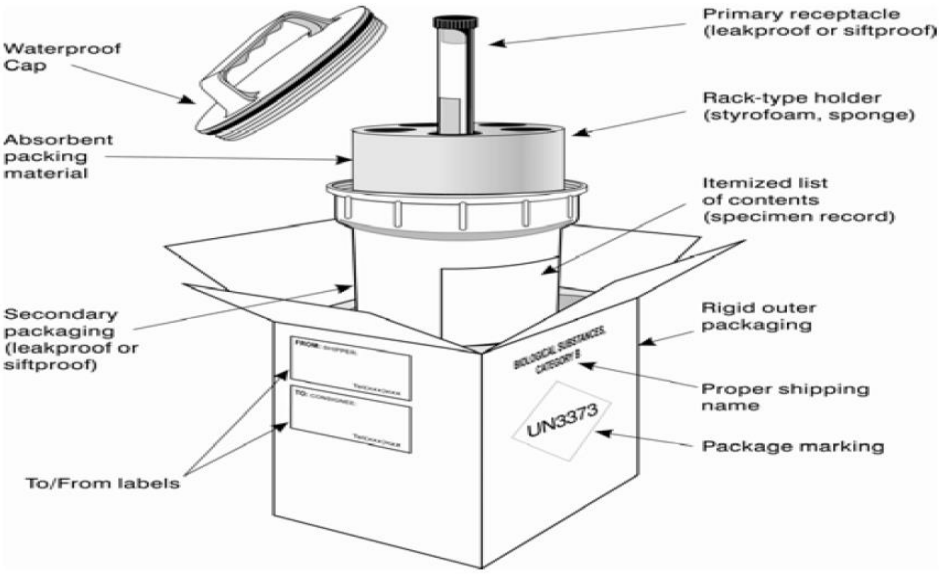


Figure 5: Example of the triple packaging system for the packing and labelling Category B infectious substances (adopted from WHO)

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
- 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

All personnel involved in transport shall undergo appropriate training. For the transport of Category A infectious substances, personnel must undergo training in accordance with the modal requirements. This shall involve attending 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. 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 shall 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.

Transport planning

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. If a carrier 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. 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. The shipper (sender, consignor), carrier and the receiver (consignee) have specific responsibilities in ensuring successful transportation.

The shipper (sender, consignor)

The shipper has the responsibility to ensure the correct classification, packaging, labelling, and documentation of all infectious substances destined for transport:

• 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.

i) The basic triple packaging system is used with the same requirements as for other means of transport

ii) . The address label shall display the word *"Lettre"* or "Letter" and the green Customs Declaration Label for Postal Mail is required for international mailing.

iii) "BIOLOGICAL SUBSTANCE, CATEGORY B" shall be identified with the white diamond label with black letters "UN 3373" .

iv) 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

Reports of infections resulting from transport-related exposures shall be documented. Incidents shall be reported to the health authorities (safety officer and Laboratory Quality Manager) and transport authorities. This applies to both categories of infectious substances, but particularly to those in Category A.