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ANCILLARY DIVISION APPROVAL MATRIX	Section / Department **LABORATORY SECTION**
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SUBSTANCES

Figure1.Packaging of Category A Infectious substances

Figure 2. Packaging of Category B Infectious substances

I. POLICY

The Guidelines on Laboratory Biosafety and Bio security are established to ensure that risk is identified; analyzed and proper corrective measures are implemented.

II. PURPOSE

To provide guidance on laboratory safety not only on the personnel but also to the environment, community and the biological agent itself.

III. BIOSAFETYPOLICYAND GUIDELINES

A. RISK ASSESSMENT

The laboratory should conduct a local risk assessment to evaluate the risk(s) arising from working with a hazard(s)and use the resulting information to determine whether risk control measures can be applied to reduce those risks to acceptable risks. This should be reviewed periodically or when changes are introduced or encountered to ensure that the laboratory is competent enough to safely perform different

laboratory tests.

B. CORE REQUIREMENTS

When handling and processing specimens, including blood for serological testing, laboratory practices and procedures should adhere to good microbiological practices and procedures (GMPP). Core requirements are a set of operational and physical elements that, when combined, should be sufficient to control the risks of most procedures with most biological agents in the laboratory. These should reflect local and international standards and best practices in bio safety that act as a set of minimum requirements and considerations that are necessary to work safely with biological agents. (See Annex I)

C. HANDLING AND TRANSPORT OF INFECTIOUS SUBSTANCES

It is often necessary to transport specimens, biological materials orwaste that are known or expected to contain biological agents between rooms, laboratories or facilities. Transferring or transporting infectious substances such as, suspected or confirmed COVID-19 infection, within or between laboratories should always be undertaken in a way that minimizes the potential for drop, spillage, collision or similar events. (See Annex II)

D. DISINFECTION AND SPILL RESPONSE

All technical procedures should be performed in a way that minimizes the generation of aerosols and droplets. Appropriated is infectants with proven activity against enveloped viruses should be used for the recommended contact time, at the correct dilution and within the expiry date after theworking solution is prepared. Procedures for cleaning and decontaminating spills must be developed for the laboratory and followed by suitably trained personnel. (See Annex I)

E. DECONTAMINATION AND WASTE MANAGEMENT

All laboratory wastes should be identified and segregated before decontamination and/or disposal. When decontamination cannot be performed in the laboratory area or onsite, the contaminated waste must be packaged in an approved (that is leak-proof) manner for transfer to another facility with decontamination capacity. (See Annex I)

F. PERSONAL PROTECTIVE EQUIPMENT (PPE)

Appropriate personal protective equipment (PPE), as determined by a detailed risk assessment, should be worn by all laboratory personnel handling these specimens. (See Annex I)

G. HEALTH AND MEDICAL SURVEILLANCE

All staff shall undergo an annual medical check-up usually to be conducted during their birth month. TheLaboratory can recommend vaccines and immunization that are necessary for the health and safety of its staff

H. BIO SAFETY MANAGEMENT

The Pathologist/ Chief Medical Technologist shall assign a staff of the Laboratory to assume the duties of Biosafety Officer (BSO). The responsibilities of the BSO shall be added to the regular duties or responsibilities of the staff assigned as BSO. The BSO should have or undergo proper training in Biosafety.The main functions of the BSO are to give advice on matters of safety and security. The following are the functions of the BSO:

a. In consultation with the Chief Medical Technologist(CMT),develop safety policies and procedures
b. Conduct Risk Assessment and give recommendations in improving safety standards in the Laboratory
c. Conduct orientation and training in bio safety; Ensure compliance to current policies and procedures
d. Investigate accidents in the Laboratory
e. Other functions related to Biosafety may be deemed necessary by the CMT and/or Pathologist.The Laboratory will maintain a Biosafety Manual that

should be readily available for all staff. The Manual shall contain all procedures and guidelines on Biosafety and Biosecurity of the Department.

IV. BIOSECURITY POLICY AND GUIDELINES

A. INFORMATION AND PERSONNEL CONTROL

Sensitive information such, diagnostic results, lists of key personnel, security plans, access codes, passwords, storage locations and biological agent inventories should not be shared with unauthorized individuals. Ensure that daily work practices and procedures are being performed by suitable personnel who behave in a reliable and trustworthy manner. Laboratory access request and approval processes for visitors and other outside personnel must be established to ensure that there is a legitimate need for access, and that appropriate vetting and escorting procedures are followed.

B. INVENTORY CONTROL

It is necessary to establish adequate control of at-risk biological agents, and to discourage theft and/or misuse. Procedures that can be used to achieve this include compilation of a detailed inventory, including description of the biological agent(s), its quantities, storage

location and use, the person responsible, documentation of internal and external transfers, and an inactivation and/or disposal of the materials.

The biological agent inventory should be up-to-date, complete, accurate and updated regularly to ensure that there is appropriate control and accountability.

C. PHYSICAL SECURITY CONTROL

These counter measures prevent unauthorized access to those who do not have a legitimate presence in the facility and have malicious intent and minimizes threat from those who have a legitimate presence in the facility such as employees and approved visitors who do not require access to a particular asset. Setting boundaries, putting access controls, intrusion detection, alarm assessment and response, increases security incrementally and forms risk-based layers of protection around the facility's assets.

D. TRANSPORT CONTROL

Ensure that biological agents are ordered from legitimate providers and that they reach their intended destination using approved couriers. Procedures for shipper, carrier and receiver responsibilities to ensure that biosecurity risks are controlled should be written and followed as appropriate. Vulnerabilities exist from the moment items are removed

from secure areas as an increased number of people may now have access to them.

Transfers should be prearranged and preapproved by responsible parties and can use chain of custody documentation(or equivalent)for proper record keeping. Inventories must be updated to reflect incoming and outgoing specimens, including internal and external transfers.

E. EMERGENCY/ INCIDENT RESPONSE

Devise a risk control strategy that could reduce the consequences of unknown events. Planning and preparation for potential incidents (such as discrepancies found in inventories, missing biological agents or unauthorized persons in the laboratory), may help detect, communicate, assess, respond to and recover from actual events. An incident response protocol should be written and followed to ensure proper reporting, and to facilitate investigation, root-cause analysis, corrective action and process improvement.

ANNEX I:

CORE REQUIREMENTS

1) GOOD MICROBIOLOGICAL PRACTICE AND PROCEDURE (GMPP)

Best Practice:

- ✓ Never store food or drink, or personal items such as coats and bags in the laboratory. Activities such as eating, drinking, smoking, and applying cosmetics are only to be performed outside the laboratory.
- ✓ Never put materials, such as pens, pencils or gum, in the mouth while inside the laboratory, regardless of whether gloves are worn or not.
- ✓ Wash hands thoroughly, preferably with warm running water and soap, after handling biological material and/or animals, before leaving the laboratory or when hands are known or believed to be contaminated.
- ✓ Ensure open flames or heat sources are never placed near flammable supplies and are never left unattended.
- ✓ Ensure that cuts or broken skin are covered before entering the laboratory.
- ✓ Before entering the laboratory, ensure that there are adequate supplies of laboratory equipment and consumables, including reagents, PPE and disinfectants, and that these items are suitable for the activities envisaged.
- ✓ Ensure that supplies are stored safely and according to storage instructions to reduce accidents and incidents such as spills, trips and falls.
- ✓ Ensure proper labeling of all biological agents and chemical and radioactive material.
- ✓ Protect written documents from contamination using barriers (such as plastic coverings), particularly those that may need to be removed from the laboratory.
- ✓ Ensure that the work is performed with care and without hurrying. Avoid working when

fatigued.

- ✓ Keep the work area tidy, clean and free of non-essential objects and materials.
- ✓ Prohibit the use of earphones, which can distract personnel and prevent equipment or facility alarms from being heard.
- ✓ Cover or remove any jewelry that could tear gloves, easily become contaminated or become fomites. Cleaning and decontamination of jewelry or spectacles should be considered, if such items are worn regularly.
- ✓ Refrain from using portable electronic devices (for example, mobile telephones, tablets, laptops, flash drives, memory sticks, cameras, orother portable devices, including those used for DNA/RNA sequencing) when not specifically required for the laboratory procedures being performed.
- ✓ Keep portable electronic devices in areas where they cannot easily become contaminated or act as fomites that transmit infection. Where close proximity of such devices to biological agents is unavoidable, ensure the devices are either protected by a physical barrier or decontaminated before leaving the laboratory.

2) PERSONNEL COMPETENCE AND TRAINING

a. General familiarization and awareness training Mandatory for ALL personnel an introduction to:

- Laboratory layout, features and equipment
- Laboratory code(s) of practice
- Applicable local guidelines
- Safety or operations manual(s)
- Institutional policies
- Local and overarching risk assessments
- Legislative obligations

- Emergency/incident response procedures

b. Job-specific training

- Training to be determined based on job function; training requirements may vary between personnel of the same job title but performing different functions

- All personnel involved in the handling of biological agents must be trained on GMPP.
- Competency and proficiency assessment must be used to identify any other specific training required, for example, by observation and/or qualification
- Proficiency in any procedure must be verified before working independently, which may require a mentorship period
- Competencies must be reviewed regularly and refresher training undertaken
- Information on new procedures, equipment, technologies and knowledge must be communicated to applicable personnel as and when available

c. Safety and security training Mandatory for ALL personnel:

- Awareness of hazards presenting the laboratory and their associated risks
- Safe working procedures
- Security measures
- Emergency preparedness and response

3) FACILITY DESIGN

- Ample space must be provided for the safe conduct of laboratory work and for cleaning and maintenance.
- Designated hand-washing basins operated by a hands-free mechanism must be provided in each laboratory room, preferably close to the exit door.
- The laboratory must be a restricted-access area. Laboratory entrance doors should have vision panels (to avoid accidents during opening), appropriate fire ratings and preferably be self-closing. Doors must be appropriately labeled with the international biohazard warning symbols wherever bio hazardous materials are handled and stored.
- Laboratory walls, floors and furniture must be smooth, easy to clean, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory.
- Laboratory bench tops must be impervious to water and resistant to disinfectants, acids, alkalis, organic solvents and moderate heat.
- Laboratory furniture must be fit for purpose. Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.
- Laboratory lighting (illumination) must be adequate for all activities. Emergency lighting must be sufficient to permit safe stopping of work as well as safe exit from the

laboratory.

- Laboratory ventilation should ensure airflows do not compromise safe working. Consideration must be given to resultant airflow speeds and directions, and turbulent airflows should be avoided; this applies also to natural ventilation.
- Laboratory storage space must be adequate to hold supplies for immediate use to prevent clutter on bench tops and in aisles. Additional long-term storage space, conveniently located outside of the laboratory room/space, should be considered.
- Space and facilities must be provided for the safe handling and storage of chemicals and solvents, radioactive materials, and compressed and liquefied gases if used. Facilities for storing food and drink, personal items, jackets and outerwear must be provided outside the laboratory.
- Facilities for eating and drinking must be provided outside the laboratory.
- First-aid facilities must be readily accessible and suitably equipped/stocked.
- Appropriate methods for decontamination of waste, for example, disinfectants and autoclaves, must be available in proximity to the laboratory. The management of waste must be considered in the design. Safety systems must cover fire, electrical emergencies and emergency/incident response facilities based on risk assessment
- There must be a reliable and adequate electricity supply and lighting to permit safe

exit.

- Emergency situations must be considered in the design as indicated in the local risk assessment and should include the geographical/meteorological context.

SPECIMEN RECEIPT AND STORAGE

- A specimen received by the laboratory must be accompanied by sufficient information to identify what it is, when and where it was taken or prepared, and which tests and/or procedures (if any) are to be performed.
- Specimens must be stored in containers that are made of adequate strength, integrity and volume to contain the specimen, leak-proof when the cap or stopper is correctly applied, made of plastic (whenever possible), free of any biological material on the outside of the packaging, correctly labeled, marked and recorded to facilitate identification, and made of an appropriate material for the type of storage required.

4) DECONTAMINATION AND WASTE MANAGEMENT

- Any surface or material known to be, or could potentially be, contaminated by biological agents during laboratory operations must be correctly managed to control biological risks.
- Proper segregation of wastes should be done before decontamination or disposal.

- Eventual treatment of the segregated waste will depend on the type of material, the biological agent(s) being handled. Additional consideration of non-biological hazards, for example, chemicals or sharps, may be required to ensure that risk control measures are in place to minimize these non-biological risks.

4.1 For general surface disinfection

4.1.1. Sodium hypochlorite (prepare 1:100 dilution)

4.1.2. 62-71% ethanol/alcohol

5.2. For decontamination of blood spills

5.2.1 Sodium hypochlorite (prepare1:100dilution)

Approximate dilution:

1:10–
11/12cupbleachinagallonofwate
r 1:100 – ¼ cup bleach in a
gallon of water

NOTE: Sodium hypochlorite is corrosive. Wiping surfaces with alcohol or water after complete surface disinfection with Sodium Hypochlorite will reduce risk of corrosion.

5.3 For space decontamination

5.3.1 Hydrogen peroxide (e.g. 3% or greater concentration) is prepared according to manufacturer's recommendation, taking in consideration the space area decontaminated and fumigation equipment to be used. Exposure time ranges from 30 minutes to one hour or more. Assistance of a qualified biomedical engineer is essential.

5) PERSONAL PROTECTIVE EQUIPMENT (PPE)

a. Laboratory Coats

Laboratory coats must be used in laboratories to prevent personal clothing from getting splashed or contaminated by biological agents. Laboratory coats must have long sleeves, preferably with fitted cuffs, and must be worn closed. Sleeves should never be rolled up. Coats must be long enough to cover the knees, but not trail on the floor. Where possible, the fabric of the laboratory coat should be splash-resistant and over lap at the front. Laboratory coats can be reusable or disposable. Reusable coats should be laundered regularly, and consideration should be given to autoclaving any visibly contaminated coats before laundering.

b. **Footwear**

Footwear must be worn in the laboratory and must be of a design that minimizes slips and trips and can reduce the likelihood of injury from falling objects and exposure to biological agents. Footwear should cover the top of the foot, and should be well-fitting and comfortable to allow personnel to perform their tasks without fatigue or distraction.

c. **Gloves**

Appropriate disposable gloves must be worn for all procedures that may involve planned or inadvertent contact with blood, body fluids and other potentially infectious materials. They must not be disinfected or reused as exposure to disinfectants and prolonged wear will reduce the integrity of the glove and decrease protection to the user. Gloves should always be inspected before use to check they are intact. Different types of gloves may be needed for different applications or other occupational hazards, such as thermal protection, or protection from sharps or against chemicals. Various sizes should be available to ensure that gloves properly fit the user to allow adequate movement and dexterity for the procedures being performed. Nitrile, vinyl and latex gloves are often used

for protection against biological agents. It should be noted that latex protein could cause allergy over time; low protein and powder-free options are available to minimize the occurrence of an allergy.

d. **Eye Protection**

Safety glasses, safety goggles, face shields (visors) or other protective devices must be worn whenever it is necessary to protect the eyes and face from splashes, impacting objects and artificial ultraviolet radiation. Eye protection must be cleaned after every use. If splashed, it must be decontaminated with an appropriate disinfectant. Personal prescription glasses (spectacles) must not be used as a form of eye protection as they do not cover enough of the face around the eyes, particularly around the side of the head.

e. **Respiratory Protection**

Respiratory protection is generally not required for protection against biological agents as a part of the core requirements. A local risk assessment should be conducted to determine whether the use of respiratory protection is needed, especially when procedures that may create aerosols and droplets will be performed outside the BSC, for example, centrifugation, handling leaking samples and procedures that can cause splashes.Though it is an essential in

cases where a biological agent is transmitted via inhalation. In this case it is recommended to use a properly fit- tested, NIOSH-approved filtering face piece respirator that provides 95 % or greater (N-95 or its equivalent). Personnel must be evaluated properly by a Medical Doctor prior use of a respirator.

6) LABORATORYEQUIPMENT

- When used effectively together with GMPP, the safe use of laboratory equipment will help minimize the likelihood of exposure of personnel when handling or manipulating biological agents.
- For equipment to effectively reduce risks, laboratory management must make sure sufficient space is provided for its use. An appropriate budget must be available for the equipment's operation and maintenance, including equipment incorporated into the facility design, which should be accompanied by specifications that outline its safety features. All personnel operating or maintaining a piece of equipment must be properly trained and be able to demonstrate proficiency.
- Records must be kept detailing equipment use, any maintenance performed, and any validation/calibration procedures undertaken and their results.

- All equipment must be checked regularly for integrity and to identify potential faults. Any faults must be reported immediately and corrective actions taken to rectify them before the equipment is used again. Performance verification must be done at regular intervals, in between Scheduled preventive maintenance and servicing, to ensure the equipment is functioning as expected.

7) EMERGENCY/INCIDENT RESPONSE

- Even when carrying out low-risk work and following all core requirements for biosafety, incidents can still occur. To reduce the likelihood of exposure to/release of a biological agent or to reduce the consequences of such incidents, a contingency plan must be developed that provides specific SOPs to be followed in possible emergency scenarios that apply to the work and local environment. Personnel must be trained on these procedures and have periodic refresher training in order to maintain competency.
- First-aid kits, including medical supplies such as bottled eye washes and bandages, must be available and easily accessible to personnel. These must be checked routinely to make sure products are within their use-by dates and are in sufficient supply.
- All incidents must be reported to the appropriate personnel, usually a

laboratory supervisor, in a timely manner. A written record of accidents and incidents must be maintained, in line with national regulations where applicable.Anyincidentthatoccursmustbereportedandinvestigatedina timely manner. Results from incident investigations must be used to update laboratory procedures and emergency response.

7.1 BIOLOGICALSPILLRESPONSE

In areas with anticipated potential risk for spills, a biological spill kit must be available and strategically located in the laboratory. A 1:100 dilution of Sodium Hypochlorite must be freshly prepared and absorbent cloth, gauze or paper towels must be available to cover the spill. A contact time of at least 30 minutes must be observed prior to cleaning the spilled area.

8) OCCUPATIONALHEALTH

- The employing authority, through the laboratory director, must take responsibility for ensuring that the health of laboratory personnel is adequately checked and reported.
- Medical examination or health status information of laboratory personnel may be required to ensure that it is safe for them to work in the laboratory. All aspects of an employee's health status must be kept confidential.

ANNEX II:

HANDLINGAND TRANSPORT OF INFECTIOUS SUBSTANCES

A. TRANSFER WITHIN THE LABORATORY

- Use sealed containers, such as screw-capped tubes. Snap-cap lids should be avoided as they are less secure.
- Use deep-sided and leak-proof trays or boxes made of smooth impervious material (for example, plastic or metal), which can be effectively cleaned and disinfected. Locking plastic containers and storage containers are an option.
- If using racks, vials or tubes, trolleys can be used for more stable transport, as they are less likely to result in multiple spillages if a worker trips or falls.
- If using trolleys, ensure they are loaded so that substances cannot fall off, for example, by securing the load or using some form of guard rail or raised sides.
- Make sure spill kits are readily available for use in the event of a spillage during transfer, and available personnel are trained in their use.

B. TRANSFER WITH IN A BUILDING

- In addition to the considerations above, the transfer of infectious substances between rooms, departments or laboratories in the same

building must be planned, organized and carried out in a way that minimizes transit through communal areas and public thoroughfares.

- Transfer containers must be suitably labelled to identify their contents, and surfaces decontaminated before leaving the laboratory. Biohazard symbols (31) should be used on containers as a heightened control measure.

C. TRANSFER WITHIN BUILDINGS ON THE SAME SITE

- Sealable plastic bags, plastic screw-top tubes and locking plastic containers can all be used in the transfer of infectious substances between buildings.
- Redundant layers of packaging should be considered. Absorbent materials should be used between layers of packaging to absorb all infectious substances, if there were leakage.
- The outermost transport container should be rigid. It can vary widely depending on the resources available. A plastic box or small plastic ice chest is one option for the transport of infectious substances between buildings on the same site, as they are secure and easily decontaminated.
- Packaging should be labeled in a way that the sender, recipient and

contents of the package are clearly identifiable. It should include biohazard symbols where appropriate.

- Personnel involved in the transfer must be provided with suitable awareness training on the risks present during the transfer process and how to safely reduce them and spill kits must be readily available and appropriate personnel trained in their use.
- Recipients must be notified in advance of the transfer occurring.

D. OFF-SITE TRANSFER OF INFECTIOUS SUBSTANCES

CLASSIFICATIONOFINFECTIOUSSUBSTANCES

	CATEGORYA	CATEGORYB
Definition	Containing a biological agent known, or reasonably expected, to cause permanent disability, or life-threatening or fatal disease.	Containing a biological agent capable of causing infection in susceptible humans or animals, but which does not meet the criteria for inclusion In Category A.

Identifiers(UN number and proper shipping name)	▪ **UN2814**: Category A infectious substances (affecting humans or zoonotic infectious substances) ▪ **UN2900**: Category A Infectious substances (affecting only animals) ▪ **UN3549**:CategoryAsolid Medical waste	▪ **UN3291**: Category B clinical or medical waste ▪ **UN3373**: Category B infectious substances(for all other substances or materials including human or animal material, cultures and biological products)
Documentation	▪ An itemized list of contents (placed between the secondary and outer packaging) ▪ Names and addresses of the shipper and the receive ▪ A dangerous goods transport document(dangerous goods declaration) ▪ Additional documentation Maybe required depending	▪ An itemized list of contents (placed between the secondary and outer packaging) ▪ Names and addresses o fthe shipper and the receiver ▪ Additional documentation may be required depending on the modal requirements (for example, airway bill for Air shipments)and/or other
	on the modal requirements (for example, air waybill for air shipments) or national regulations(for example, import/export permits)	national requirements (for example, import/export permits)

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Packaging	▪ Triple packaging required to comply with UN packing instruction P620 ▪ Packaging must show a UN specification mark, indicating compliance with testing requirements for Category A infectious substances packaging	▪ Packaging must show a UN specification mark, indicating compliance with testing requirements for Category A infectious substances packaging ▪ UN3373: Triple packaging required (for air transport, either the secondary or outer package must be rigid) which compiles with and is packaged according to UN packing instructionP650

UN=United Nations

Exempt human (or animal) specimens

Substances or materials derived from human or animal patients (that are clinical specimens) for which there is a minimal likelihood that infectious biological agents are present are defined as exempt human or exempt animal specimens. They are still required to be packaged using redundant layers of packaging in a triple-layered system containing primary, secondary and outer packaging of adequate strength for the substance being transported.

TRIPLE PACKAGING OF INFECTIOUS SUBSTANCES

1. Primary Packaging/Receptacle

   - Contains the infectious substance must be watertight, leak-proof and appropriately labelled as to its contents.
   - Wrapped in an absorbent material to absorb its contents in the event spillage occurs.
   - If multiple primary receptacles are packed together, cushioning material must be used to prevent contact between them.

2. Secondary watertight, leak-proof packaging

   - Encloses and protects the primary receptacle(s). Several wrapped primary receptacles may be placed in a single secondary packaging.

3. Third layer/Outer packaging

   - Protects the secondary packaging from physical damage while in transit. It is between the second and third outer layers that coolants, such as dry ice or liquid nitrogen, can be used if necessary.
   - Coolants are also classified as dangerous goods and may therefore be subject to additional requirements themselves, as outlined in applicable regulations.

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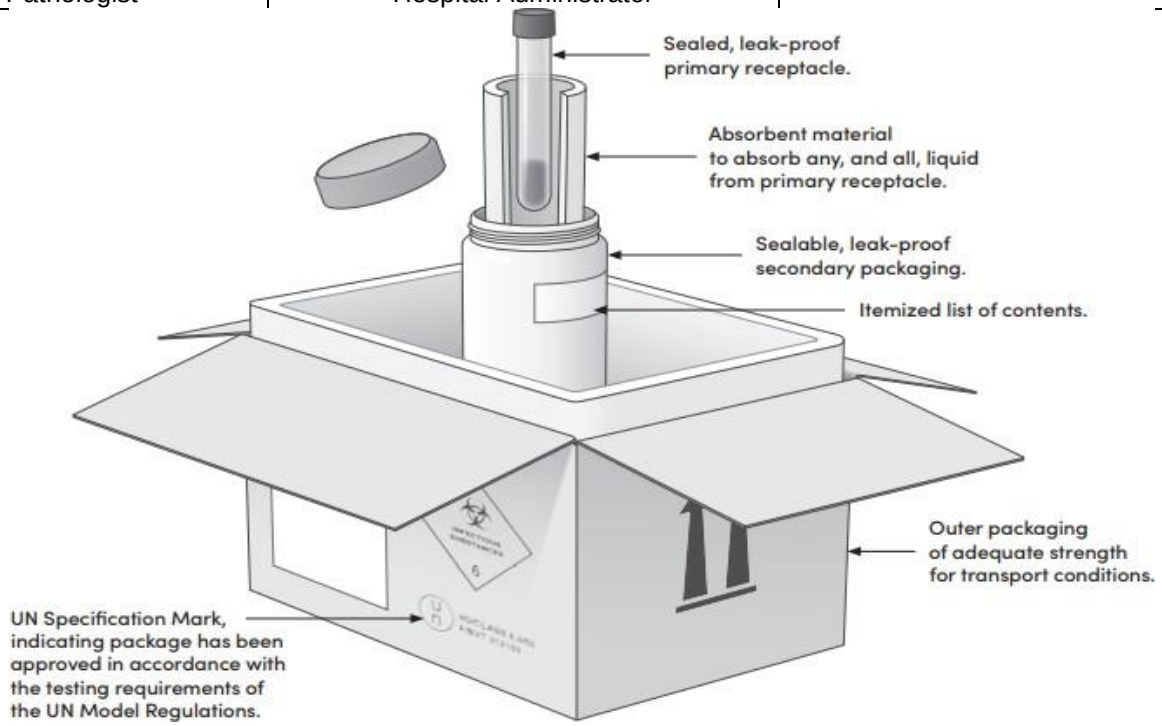
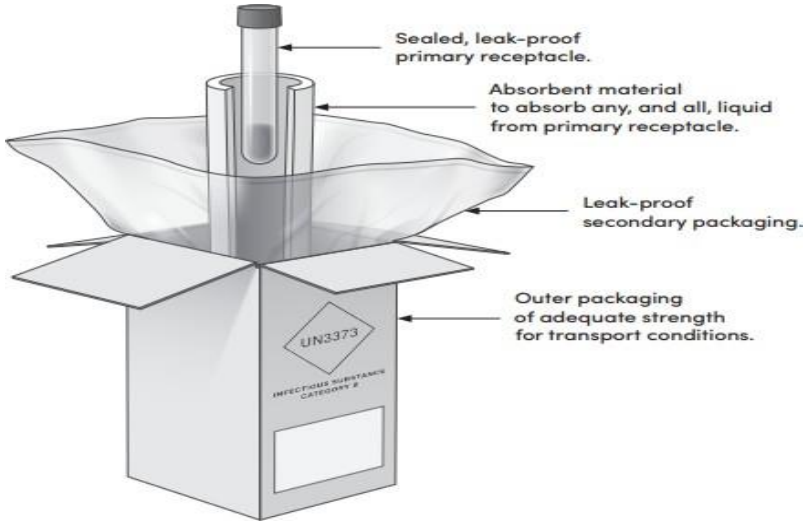


CATEGORY A PACKAGING: IATAPI620

- Primary container is leak-proof
- Secondary container is leak-proof
- Outer container is rigid
- UN specification marking:
- Pressure tested at 96 kPa
- Drop tested from 9 meters
- Puncture tested at 7 kg
- Stacking tested
- Shipper must be trainedFigure2.ExampleoftriplepackagingofCategoryBInfectioussubstances



CATEGORY B PACKING REQUIREMENTS

- Primary container is leak proof
- Secondary container is leak proof
- Either the primary or the secondary container must be pressure tested at 95 kPa
- Eitherthesecondaryoroutercontainerisrigid.Iftheshipmentistran sportedby air, the outer container must be rigid.
- Drop tested from 1.2 meters