# Transportation of Biological Materials

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MyOHUN MALAYSIA ONE HEALTH UNIVERSITY NETWORK

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# Learning Objective and Outcome

| Learning objectives | Learning outcomes |
| --- | --- |
| Participants will be able to<br>○ identify the differences between internal and external transportation<br>○ recognize international and national regulation requirements<br>○ understand procedures and requirements needed for transporting biological materials<br>○ understand biosecurity concern in transportation biological materials | Participants will be able to<br>○ describe the differences between internal and external transportation<br>○ follow international and national regulation requirements<br>○ explain procedures for transporting biological materials<br>○ discuss biosecurity concern in transportation biological materials |

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# What is Transport???

- Ferrying a person or material from one point to another
- This module focus on transporting of Biological materials

# Where would your transport biological materials?





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# Introduction

**Transport** – movement of biological agent outside a restricted area.

- Research Labs
- Public Health Laboratories
- Diagnostic laboratories
- Hospitals


Reasons for transportation of biological materials?

- ✓ For epidemiology study
- ✓ For research
- ✓ For diagnosis

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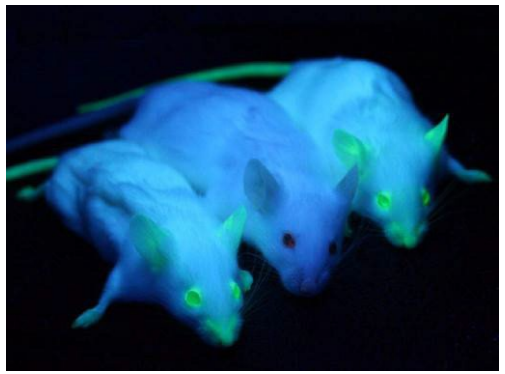
# Introduction

- For the purpose of transport, materials from the laboratory that may contain biological agents are known as **infectious substances**; these include cultures, patient or animal specimens, infected body parts or organs, and biological products such as vaccines or similar therapeutic products.

- **Genetically modified organisms**, if they are capable of causing infection in humans or animals, will also fall under this category.

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# Internal Transport

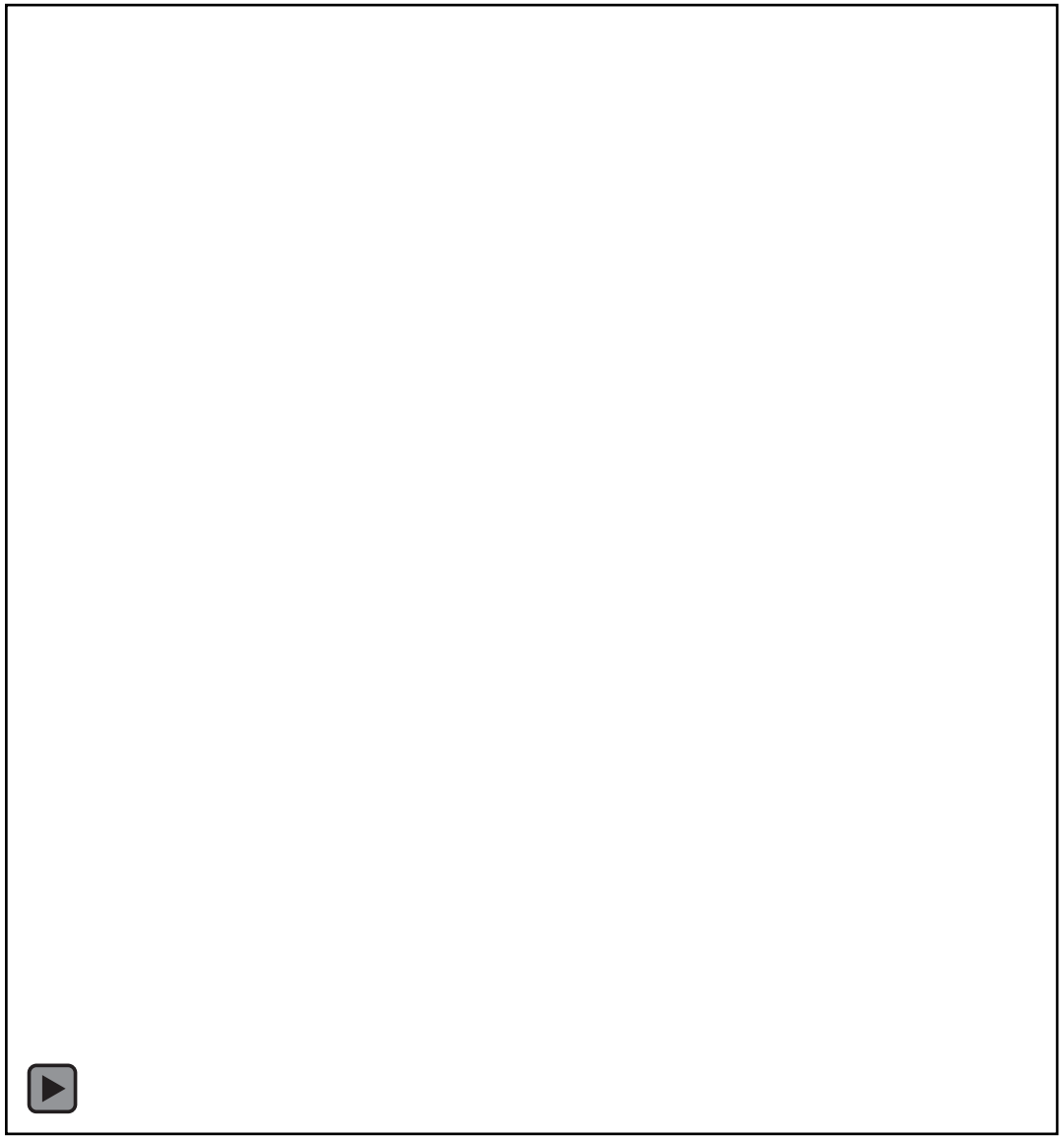
- Internal Transport – movement to & from restricted area within a facility or between facilities.
- This involves:

(i) **Personnel** (labs, shipping areas, receiving areas, disposal areas)

(ii) **Containers** – leak proof, sealed

(iii) **Pre-approval**, if required

(iv) **Chain of custody** – to be decided in the organisation/IBC.



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# External Transport

- Involves movement of biological materials from one facility to another.
- This involves:

(i) **Commercial carriers**

(ii) **International or National Regulations & Standards**

(iii) **Effective transport of frozen samples**

(iv) **Must be cost-effective**

(v) **Personnel** (labs, shipping areas, receiving areas, disposal areas)

(vi) **Containers** – leak proof, sealed

(vii) **Pre-approval**, if required

(viii) **Chain of custody** – to be decided in the organisation/IBC.


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# Questions need to be asked before transporting infectious materials.

**How are biological substances transported in and out of your facility?**

- Where are materials in your lab coming from and how?
- Where are materials going to and how?
- To whom are materials coming from or going to?
- Do you have authorization?
- Are there any SOPs or regulations that you follow in your facility?

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# STANDARD OPERATING PROCEDURE FOR TRANSPORT OF BIOLOGICAL SPECIMENS IN MALAYSIA

MINISTRY OF HEALTH MALAYSIA
1st Edition
2012

# International Air Transport Association Dangerous Goods Regulations

- IATA - Represents, leads and serves the air industry. Founded in Havana, Cuba, on 19 April 1945.
- It is the trade association for the world's airlines. Has 290 member airlines and air carriers (82% of Int Air traffic)
- Malaysia is a member
- International Standard – most air shipments will be inspected based on IATA requirements.
- Generally MOST RESTRICTIVE. Support many areas of aviation activity and help formulate industry policy on critical aviation issues.
- Incorporates all International Civil Aviation Organization (ICAO)/United Nations (UN) requirements and most national requirements.
- http://www.iata.org/whatwedo/cargo/dangerous_goods


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# Definitions of Dangerous Goods by IATA

- Dangerous goods are articles or substances, which are capable of posing a risk to health, safety, property or the environment and which are shown in the list of dangerous goods in the regulations or which are classified according to the regulations.
- Dangerous goods are defined as those goods which meet the criteria of one or more of the **nine UN hazard classes** and, where applicable, to one of three UN packing groups according to the provisions of this section.
- The **nine classes relate to the type of hazard**, whereas the **packing groups relate to the applicable degree of danger within the class**.
- Some of the 9 nine classes are broken down into divisions.

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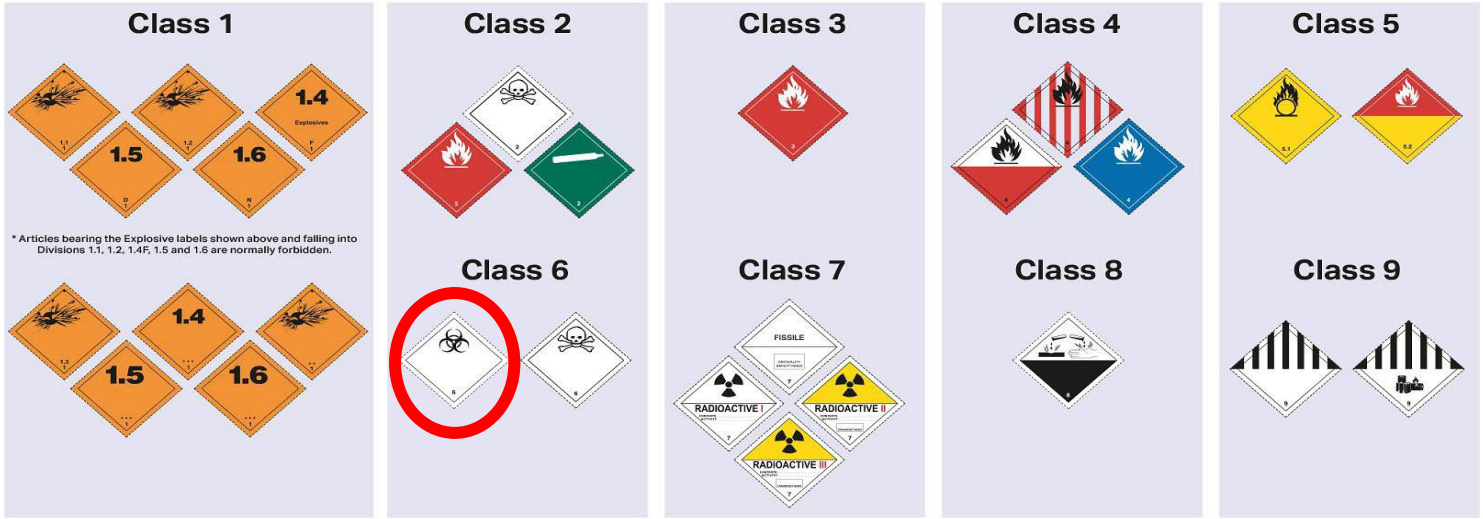
# DANGEROUS GOODS

## Hazard and Handling Labels

### Hazard Labels




### Handling Labels and Marks


Minimum size for hazard labels 100 x 100 mm. For full information on hazard and handling labels for dangerous goods refer to the current edition of the IATA Dangerous Goods Regulations.
For further information on Dangerous Goods, contact us at dangood@iata.org.
Order products online at www.iataonline.com or visit www.iata.org.

**www.iata.org/labels**

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IATA

- Class 1 Explosives
- Class 2 Gases
- Class 3 Flammable Liquids
- Class 4 Flammable Solids
- Class 5 Oxidizing Substances and Organic Peroxides
- Class 6 Toxic and Infectious Substances
  - 6.1 Toxic Substances
  - 6.2 Infectious Substances
- Class 7 Radioactive Material
- Class 8 Corrosives
- Class 9 Miscellaneous Dangerous Goods

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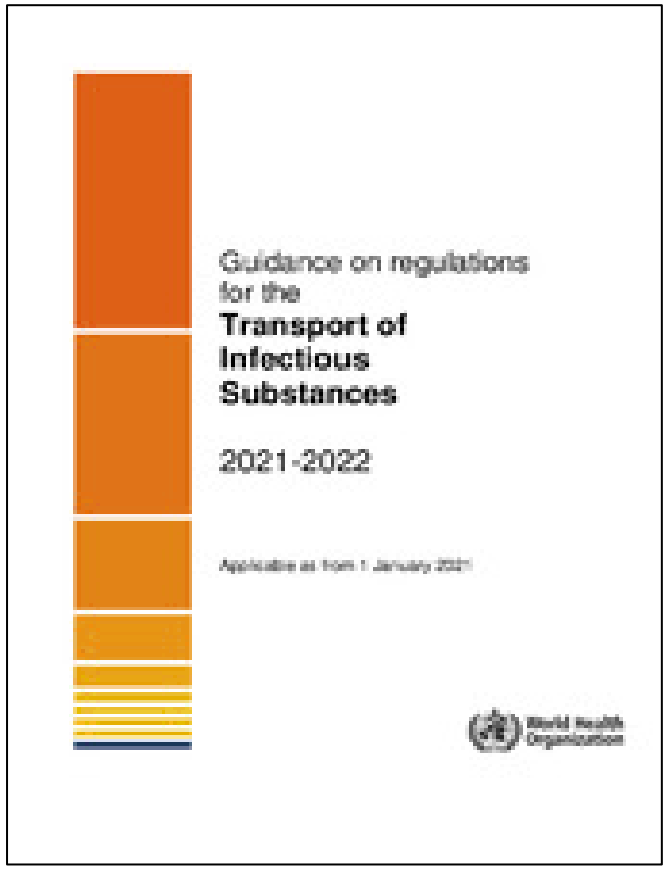
# WHO Guidance on Regulations for the Transport of Infectious Substances




https://www.who.int/publications/i/item/9789240019720

# Classification of biological materials for shipping

- The classification of biological materials are **based on the level of the infectivity/virulence** of the biological material and the **mode(s) of the transportation** used while acknowledging the regulatory requirements where applicable.
- **Infectious substances** shall be classified as Division 6.2 dangerous goods and assigned the appropriate UN number: **UN 2814, UN 2900, UN 3291** or **UN 3373** and classified either as **Category A or Category B**.
- There is no direct relationship between Risk Groups of microorganisms and categories A and B.

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# Category A, UN 2814

- Category A biological materials comprise infectious substances which are 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.**
- **The proper shipping name for UN 2814 is "INFECTIOUS SUBSTANCE, AFFECTING HUMANS".**
- Packing instruction **P620 (UN) or PI 620 (IATA)** apply to these substances.

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# Category A, UN 2900

- Infectious substances which cause disease **only in animals** shall be assigned to UN 2900.
- The proper shipping name for UN 2900 is "**INFECTIOUS SUBSTANCE, AFFECTING ANIMALS ONLY**".
- Packing instruction **P620 (UN) or PI 620 (IATA)** apply to these substances.

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# UN 2814 OR UN 2900 ?

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 judgment concerning individual circumstances of the source human or animal.

- Infectious substances meeting these criteria which cause disease in humans or both in humans and animals shall be assigned to **UN 2814.**

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# Category B, UN 3373

- Consists of all the non-deadly pathogenic agents; the low to medium risk infectious substances.
- 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 proper shipping name of UN 3373 is **BIOLOGICAL SUBSTANCE, CATEGORY B.** (The shipping name DIAGNOSTIC SPECIMENS, CLINICAL SPECIMENS has been phased out.)
- Packing instruction **P650 (UN) or PI 650 (IATA)** apply to these substances.

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# Which is the category for biohazard waste?

# Medical or clinical wastes

- Medical or clinical wastes are wastes derived from the medical treatment of animals or humans or from bio-research.
- 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 Category B infectious substances, 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).


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# Which is the category for GMO?

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# Genetically modified organisms

- Genetically modified microorganisms and organisms are microorganisms and organisms in which **genetic material has been purposely altered** through genetic engineering in a way that does not occur naturally.
- Those genetically modified microorganisms and organisms that do not meet the definition of an infectious substance but which are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction shall be assigned to **UN 3245** and shipped following Packing Instruction **P904 (ICAO/IATA PI913)**.



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# Category C (Malaysia only)

- Category C covers human, animal or plant sample including excreta, secreta, blood and its components, tissues and tissue fluids, **not belonging to Category A or B** as listed in IATA Dangerous Goods Regulation.
- Category C biological materials comprises **substances with a low probability of causing disease in humans, animals and plants** that could cause community concerns if the specimen was to leak from its packaging.
- If transported by **air, IATA regulations for Exempt Patient Specimens** shall be followed.
- If transported by **land, Category C shall be packaged, marked, documented and transported according to the requirements in Malaysian Standard MS 1042-3**.

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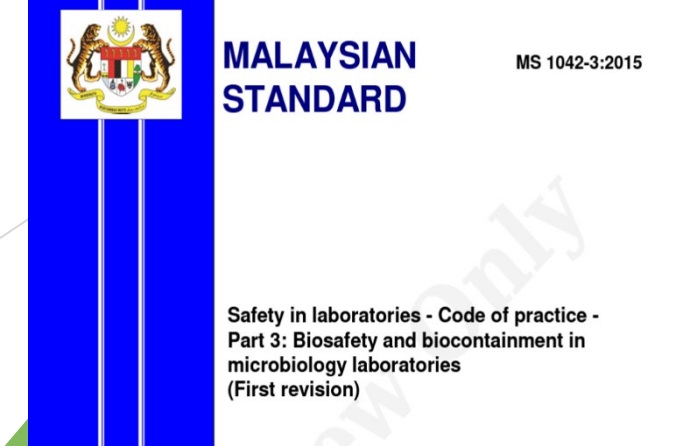


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# Exempt substances

- Human or animal specimens (patient specimens) for which there is minimal likelihood that pathogens are present are not subject to these Regulation 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.

**For a comprehensive list of Exempt Substances, please refer to the current edition of the IATA Dangerous Goods Regulations.**

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# Scenario

- Nasopharyngeal swabs are randomly collected from office workers for seasonal flu prevalence survey.
- The swabs are transported to a local clinical laboratory for analysis (ground transport only)

**Discussion:**

- Are they infectious substances?
- How would you classify these as Category A or B or C?


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# Scenario

- The clinical lab cultures the swabs and determines that swabs from 3 individuals appear to be *COVID-19* positive.
- These swabs are preserved and shipped to MKK for verification and genome sequencing.
- How would you classify these specimens as Category A or B? Why?

# How biological sample should be packaged before transporting?





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# What is Triple Packaging?

- Three layer of protection
- Primary container: Robust, watertight and leak proof packaging with seal containing the infectious substance.
- Secondary container: Robust, watertight and leak proof packaging with seal to enclose and protect the primary container. Several cushioned primary receptacles can be placed in one secondary packaging, but sufficient absorbent material should be used to absorb all fluid in case of breakage.
- Outer container: Robust outer container with suitable cushioning material and relevant labels to enclose and protect the secondary container. The outer packaging should protect contents from physical damage during transit.

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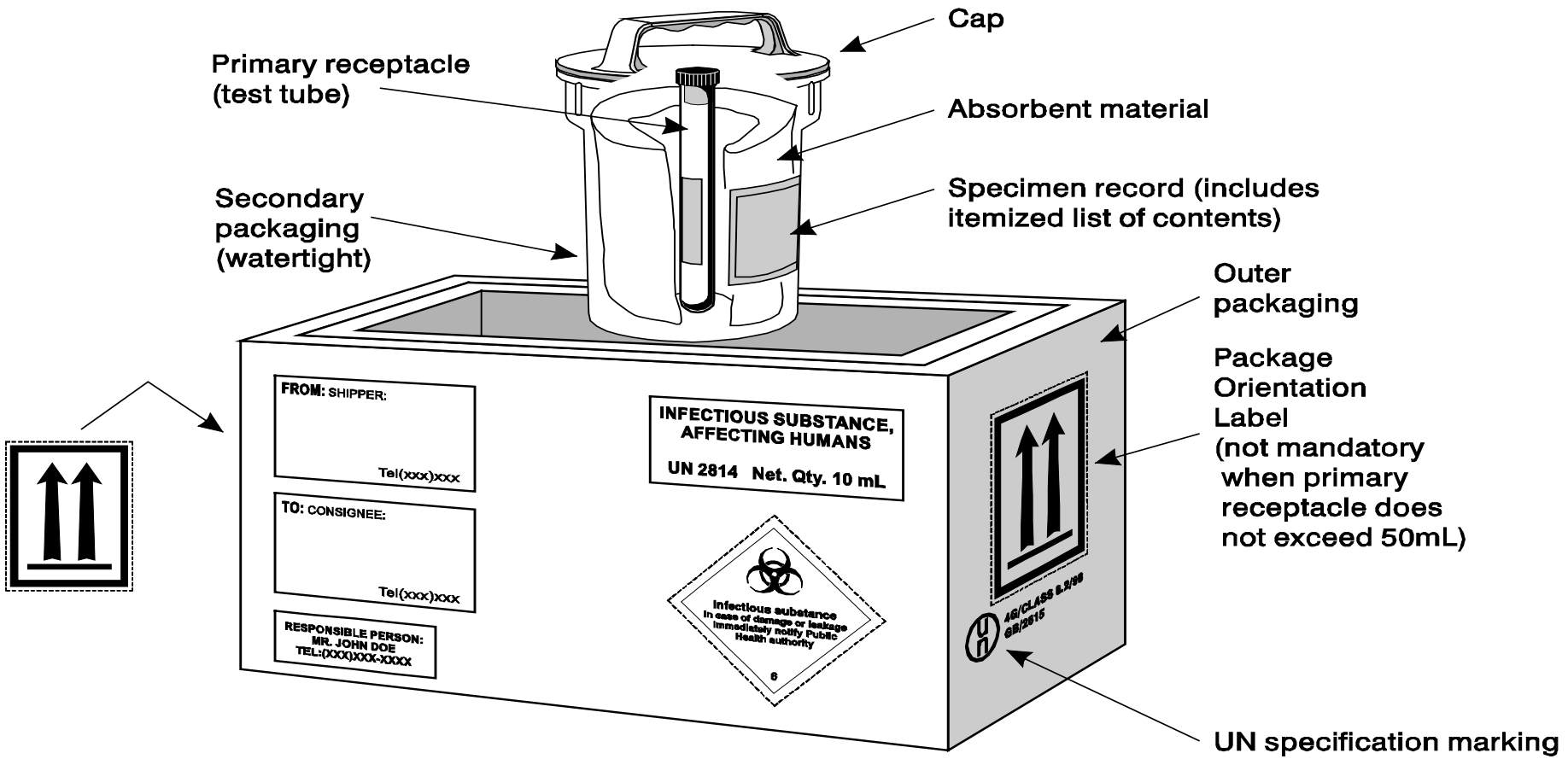
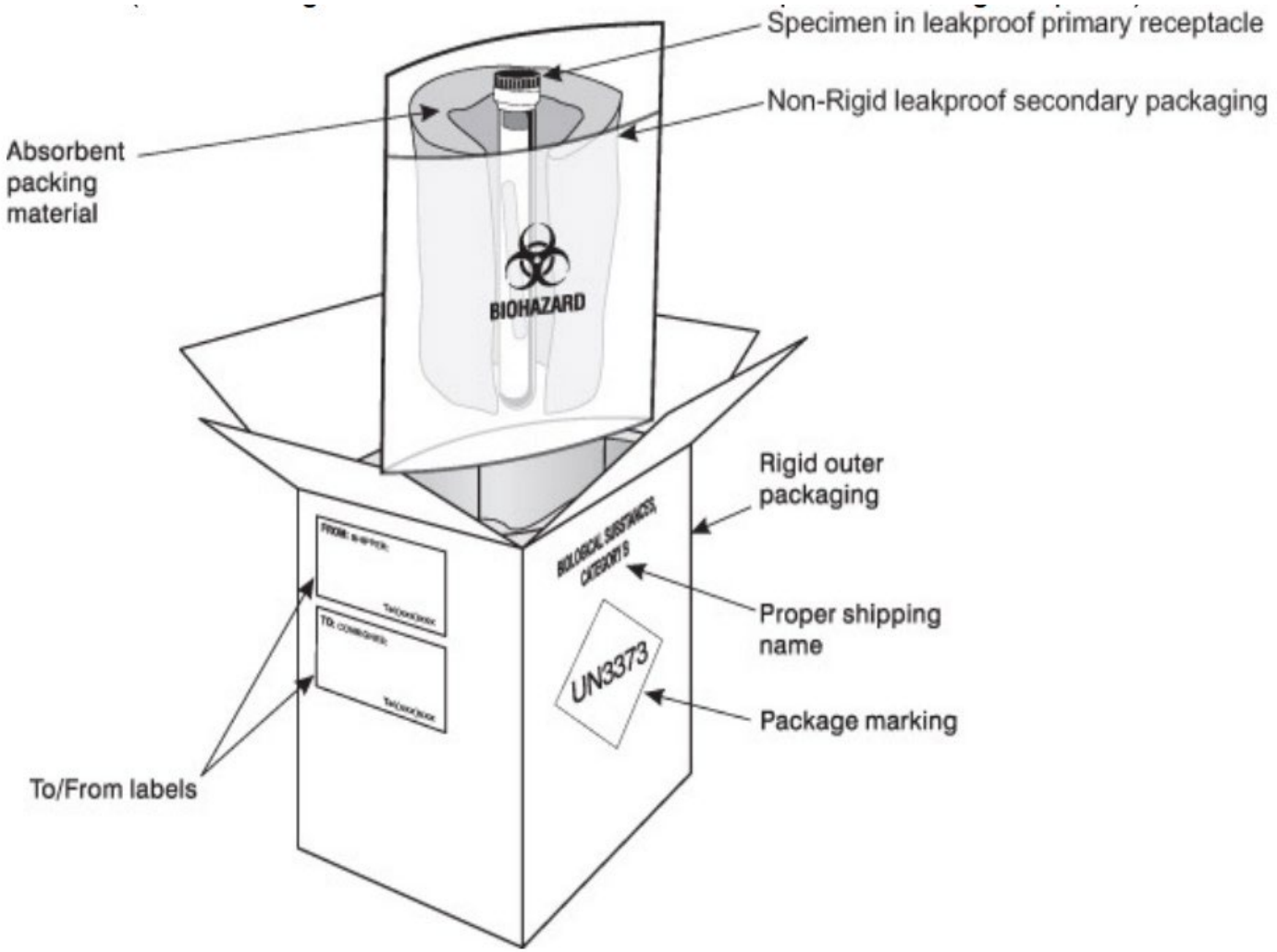
# TRIPLE PACKAGING (P620)



# TRIPLE PACKAGING (P650)

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# Can you think of any Biosecurity concern in transportation of biological materials

- Transport security Pillar
- Chain of custody (C-O-C)
- Person that is in-charge
- Vulnerability of the sample being stolen

# Training Requirements

- Category A
  - Full day certification
  - Competency demonstration (e.g. written exam & hands-on demonstration)
- Category B
  - Training but no certification requirement
  - Knowledge of requirements
- Category C
  - No formal training requirements

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# Key messages

- IATA regulatory requirements is the best way to ensure regulatory compliance.
- Regulations have specific definitions and criteria for Classification of Category A or B or C.
- Every dangerous good is assigned a specific, internationally recognized proper shipping name and corresponding UN number.
- All biological agents must be “triple packed”.
- Before shipping high risk agent, there are many additional considerations including security.

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# DON'T TRANSPORT/SHIP IF YOU DON'T KNOW

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# THANK YOU

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