Infectious Substance Transport

Laboratory Biosecurity and Biosafety

for BSL3 Laboratories

Bogor, Indonesia

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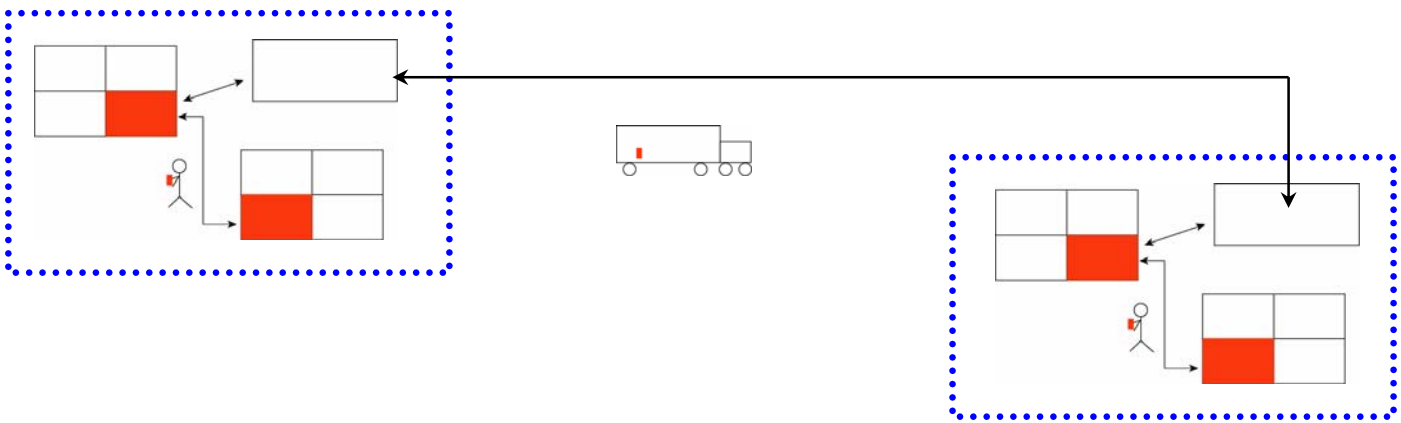
Infectious Substance Transport

- **Transport – movement of biological material outside of a restricted area**
  - **Research labs**
    - Sample transfers are necessary for study and to further research
  - **Public health labs and diagnostic labs**
    - Sample transfers are necessary for diagnosis and analysis
- **Transport can occur**
  - **Across international borders**
  - **Within a country**
  - **Within a facility**



Internal Transport

- Movement of materials to and from restricted areas within a facility

- May involve personnel from
  - Labs
  - Shipping areas
  - Receiving areas
  - Disposal areas (e.g. autoclave and incinerator rooms)
- Move materials safely and securely
  - SOPs
  - Leak-proof containers
  - Pre-approval?
  - Chain of custody?

External Transport

- Movement of materials from one facility to another facility
- May involve commercial carriers
- Occur within a wide array of international and state regulations and standards
- Must be able to move frozen materials efficiently
- Need to be cost-effective

Development of Regulations for Transport of Infectious Substances

UN Committee of Experts on Transport of Dangerous Goods

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Model Regulations on the Transport of Dangerous Goods

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ADR (road) | **RID (rail)** | **IMO (sea)** | **ICAO (air)** → **IATA (air)**

National Regulations

UN Committee of Experts on Transport of Dangerous Goods

- **Voting members**
  - **Representatives from ~ 30 countries**

- **Non-voting observers and advisors**
  - **ICAO (International Civil Aviation Organization)**
  - **IATA (International Air Transport Association)**
  - **DGAC (Dangerous Goods Advisory Council)**
  - **EBSA (European Biological Safety Association)**
  - **ABSA (American Biological Safety Association)**
  - **WHO (World Health Organization)**
  - **others**

What are Dangerous Goods?

- **Definition from DGR**
  - **“Dangerous goods are articles or substances which are capable of posing a risk to health, safety, property, or the environment and … which meet the criteria from one or more of the nine UN hazard classes”**
- **Dangerous goods are classified into:**
  - **9 hazard groups**
  - **Some classes are further divided into divisions**
  - **Some classes or divisions have packing groups to identify how dangerous a substance is**
    - **Packing Group I – highest danger**
    - **Packing Group II – medium danger**
    - **Packing Group III – low danger**

Nine Classes of Dangerous Goods

- Class 1 Explosives
  - 1.1 Mass explosion hazard
  - 1.2 Projection hazard
  - 1.3 Fire hazard, minor blast hazard, and/or minor projection hazard
  - 1.4 No significant hazard
  - 1.5 Very insensitive, mass explosion hazard
  - 1.6 Extremely insensitive explosive, no mass explosion hazard
- Class 2 Gases
  - 2.1 Flammable gas
  - 2.2 Non-flammable, non toxic gas
  - 2.3 Toxic gas
- Class 3 Flammable Liquids
- Class 4 Flammable Solids
  - 4.1 Flammable solid
  - 4.2 Substances liable to spontaneous combustion
  - 4.3 Substances which, in contact with water, emit flammable gas
- Class 5 Oxidizing Substances and Organic Peroxides
  - 5.1 Oxidizer
  - 5.2 Organic peroxide
- 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

Division 6.2 Infectious Substances

- **Infectious substances (DGR 3.6.2.1.1)**
  - **“Infectious substances are substances known to contain or reasonably expected to contain pathogens”**
  - **Category A and Category B**
- **Biological products (DGR 3.6.2.1.3)**
  - **“Biological products derived from living organisms. These are manufactured and distributed in accordance with the requirements of national governmental authorities … and are used for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto”**
  - **If infectious, then 6.2, otherwise not restricted**
- **Genetically modified microorganisms and organisms (DGR 3.6.2.1.3)**
  - **“These are microorganisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally”**
  - **If infectious, then 6.2; otherwise class 9 (miscellaneous)**
- **Clinical or medical waste (DGR 3.6.2.1.5)**
  - **“Wastes derived from the medical treatment of humans or animals or from bio-research”**
  - **Category A or B as appropriate**

Category A Infectious Substances

- 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
- Examples of Category A infectious substances are given in a list
  - List is not exhaustive
- Packaging
  - Most durable triple packaging
  - Full dangerous goods documentation
  - PI 602

Indicative examples of infectious substances included in Category A

UN 2814 Infectious substances affecting humans	***Bacillus anthracis*** **(cultures only)** ***Brucella abortus*** **(cultures only)** ***Brucella melitensis*** **(cultures only)** ***Brucella suis*** **(cultures only)** ***Burkholderia mallei [Pseudomonas mallei – Glanders]*****(cultures only)** ***Burkholderia*** **pseudomallei** ***[Pseudomonas pseudomallei]*** **(cultures only)** ***Chlamydia psittaci*** **[avian strains] (cultures only)** ***Clostridium botulinum*** **(cultures only)** ***Coccidioides immitis*** **(cultures only)** ***Coxiella burnetii*** **(cultures only)** **Crimean-Congo hemorrhagic fever virus** **Dengue virus (cultures only)** **Eastern equine encephalitis virus (cultures only)** ***Escherichia coli*****, verotoxigenic (cultures only)** **Ebola virus** **Flexal virus** ***Francisella tularensis*** **(cultures only)**

Indicative examples of infectious substances included in Category A

UN 2814 Infectious substances affecting humans	**Guanarito virus** **Hantaan virus** **Hanta virus pulmonary syndrome** **Hendra virus** **Hepatitis B virus (cultures only)** **Herpes B virus (cultures only)** **Human immunodeficiency virus (cultures only)** **Highly pathogenic avian influenza virus (cultures only)** **Japanese Encephalitis virus (cultures only)** **Junin virus** **Kyasanur Forest disease virus** **Lassa virus** **Machupo virus** **Marburg virus** **Monkeypox virus** ***Mycobacterium tuberculosis* (cultures only)** **Nipah virus** **Omsk hemorrhagic fever virus**

Indicative examples of infectious substances included in Category A

UN 2814 Infectious substances affecting humans	**Poliovirus (cultures only)** **Rabies virus** ***Rickettsia prowasekii* (cultures only)** ***Rickettsia rickettsii* (cultures only)** **Rift Valley fever virus** **Russian spring-summer encephalitis virus (cultures only)** **Sabia virus** ***Shigella dysenteriae type 1* (cultures only)** **Tick-borne encephalitis virus (cultures only)** **Variola virus** **Venezuelan equine encephalitis virus** **West Nile virus (cultures only)** **Yellow fever virus (cultures only)** ***Yersinia pestis* (cultures only)**

Indicative examples of infectious substances included in Category A

UN 2900 Infectious substances affecting animals only	**African horse sickness virus** **African swine fever virus** **Avian paramyxovirus Type 1 [Newcastle disease virus]** **Bluetongue virus** **Classical swine fever virus** **Foot and mouth disease virus** **Lumpy skin disease virus** ***Mycoplasma mycoides* [Contagious bovine pleuropneumonia]** **Peste des petits ruminants virus** **Rinderpest virus** **Sheep-pox virus** **Goatpox virus** **Swine vesicular disease virus** **Vesicular stomatitis virus**

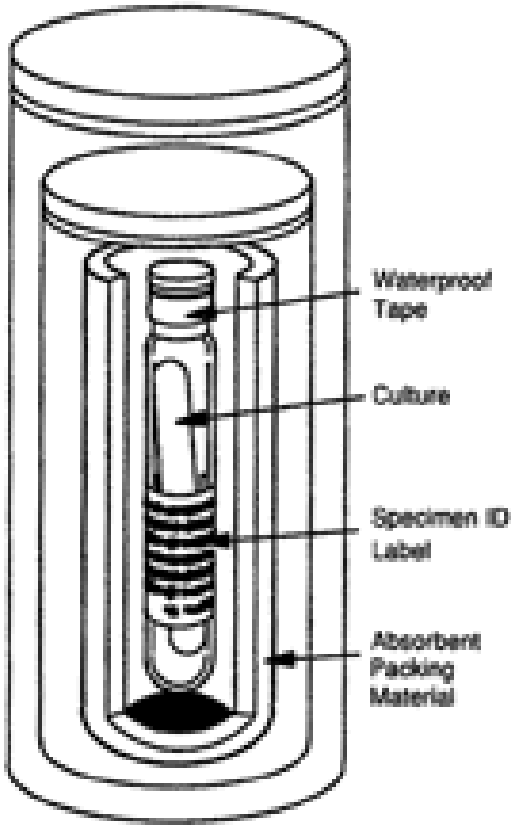
Category B Infectious Substances

- Infectious substances not included in Category A
- Cultures of “B” must be packed and shipped as “A”
- Packaging
  - Less stringent triple packaging
  - No dangerous goods documentation required
  - PI 650

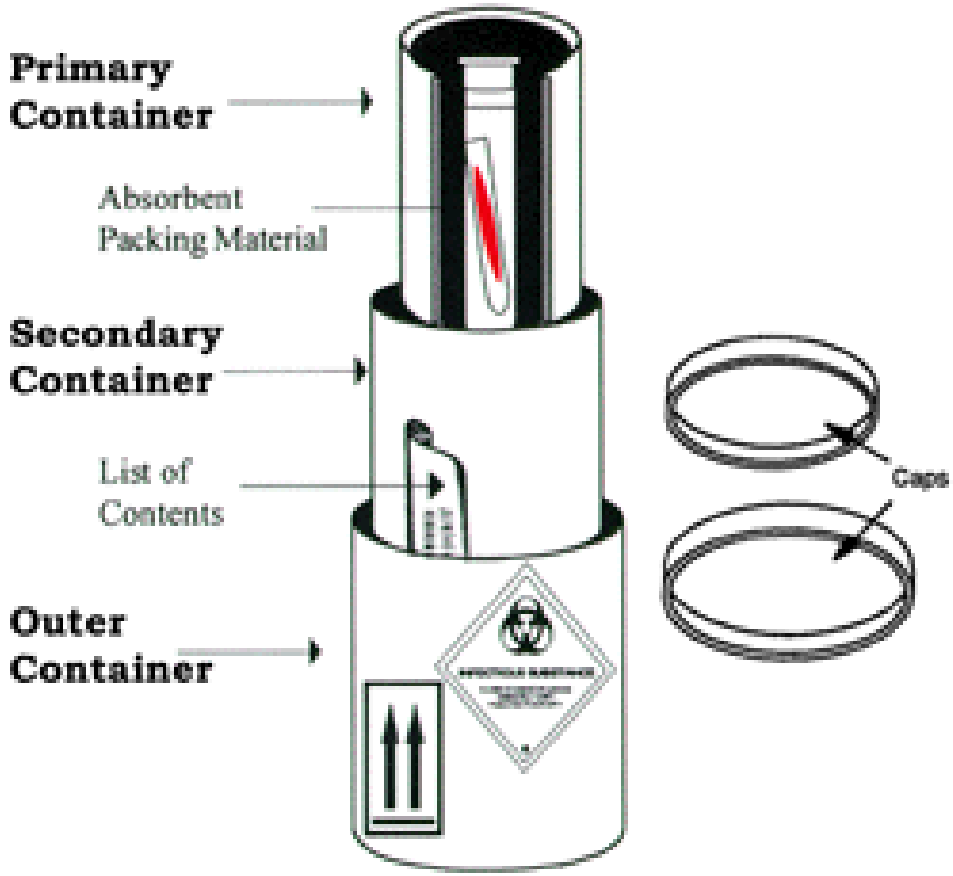
Exemptions

- **Blood or blood products for transfusion**
- **Tissues or organs for transplant**
- **Materials with low probability of containing infectious substances (foodstuffs, water samples, living persons)**
- **However, WHO recommends that all specimens of human or animal origin be packaged in P650 as a minimal standard!**

INFECTIOUS SUBSTANCE PACKAGING

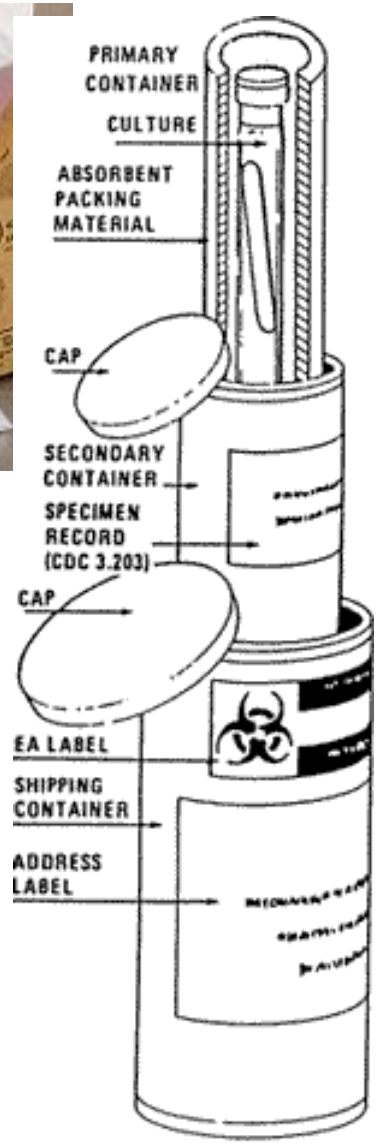


Cross Section of Proper Packing



Safe transport of infectious materials

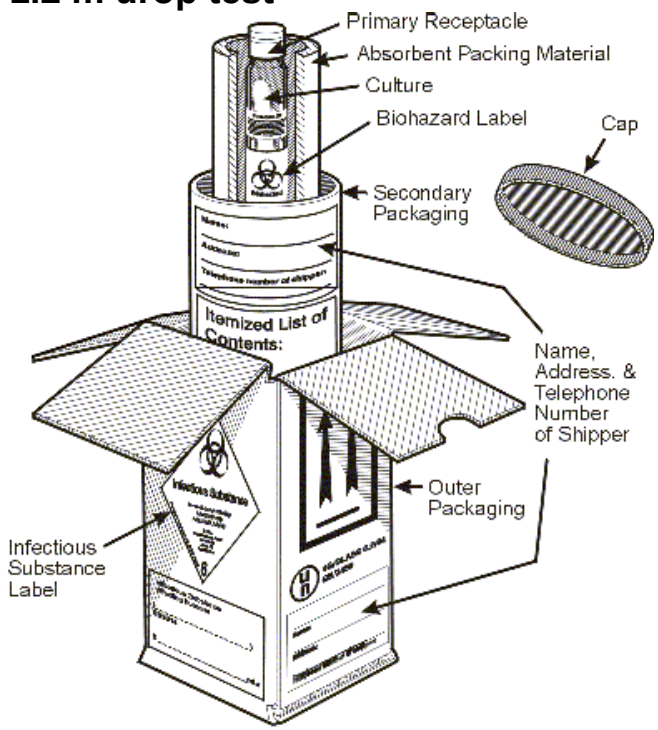
- **Permit to Ship**
  - **Classify infectious substances**
    - **Category A vs Category B**
- **Packaging**
  - **Packaging material then determined**
    - **Must be UN certified**
    - **Triple-pack system**
  - **Overpacks and permitted quantities**
    - **50 ml on commercial aircraft**
    - **4 liters on cargo**
    - **Overpack quantity**
  - **Re-use of materials**
  - **Dry-Ice**
    - **Class 9 y**
    - **6 lbs. For 48 hours**
- **Training/Certification**



Packaging

- **Category A Infectious Substances (602)**
  - **UN specification triple packaging**
    - **Watertight primary**
    - **Watertight secondary**
    - **Absorbing material sufficient for entire contents**
  - **Tests**
    - **9 m drop test (dry, wet, 0 F, dry ice)**
    - **Puncture test**
    - **Stacking test**
    - **Internal pressure test – 95 kPa**

- **Category B Infectious Substances (650)**
  - **Non-specification package**
    - **Leak-proof primary**
    - **Secondary packaging**
    - **Outer packaging**
  - **Tests**
    - **1.2 m drop test**



Transport Security: Chain of Custody (CoC)

- Aims to protect sample by documenting
  - All individuals who have control of sample
  - Secure receipt of material at appropriate location

- Chain of custody documentation includes
  - Description of material being moved
  - Contact information for a responsible person
  - Time/date signatures of every person who assumes control

Transport Security: Process

- Responsible authority pre-approves all transport
- Transport should be documented in lab records
- Transport is controlled and documented in delivery records
- Timely shipping methods are used
- Chain of Custody is maintained
- Notification of successful receipt

Transport Security: Facility Responsibilities

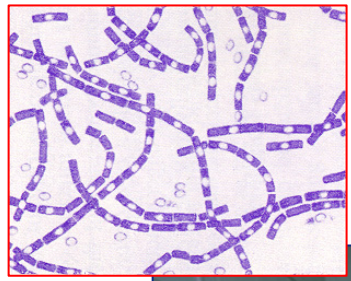
- **Personnel security**
  - **For people who have access to dangerous pathogens and toxins or information during transfers**
- **Establish chain of custody (CoC)**
  - **Record all individuals who have contact with the dangerous pathogens and toxins**
- **Provide physical security**
  - **For packages that need temporary storage**
- **Protect transport documentation**
- **Determine who is able to authorize, transport, and receive dangerous pathogens and toxins**

Carrier Security

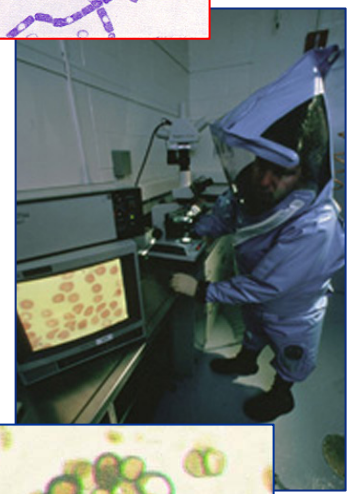
- **Carriers should provide security by**
  - **Ensuring reliable and trustworthy people handle the package**
  - **Controlling access to transport facilities, docks, and vehicles**
  - **Tracking shipping progress**
  - **Providing ongoing security training for employees**

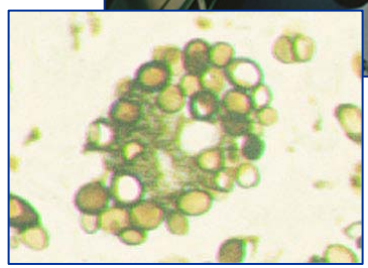
US Requirements for Infectious Substance Transport Security

- Infectious substances (Class 6.2) and toxins (Class 6.1) are defined as Hazardous Material
- 49 Code of Federal Regulations (CFR) 172 (2003) – HM 232 – mandates security measures for the transport of some Hazardous Material
  - Select Agents regulated under 42 CFR 73 require Hazardous Material transport security measures
- Hazardous Material regulated security requirements include:
  - Training
    - Security awareness training
    - Specific training as appropriate
  - Written security plan
    - Based on assessment of transportation security risks
    - Address personnel security, unauthorized access, en route security



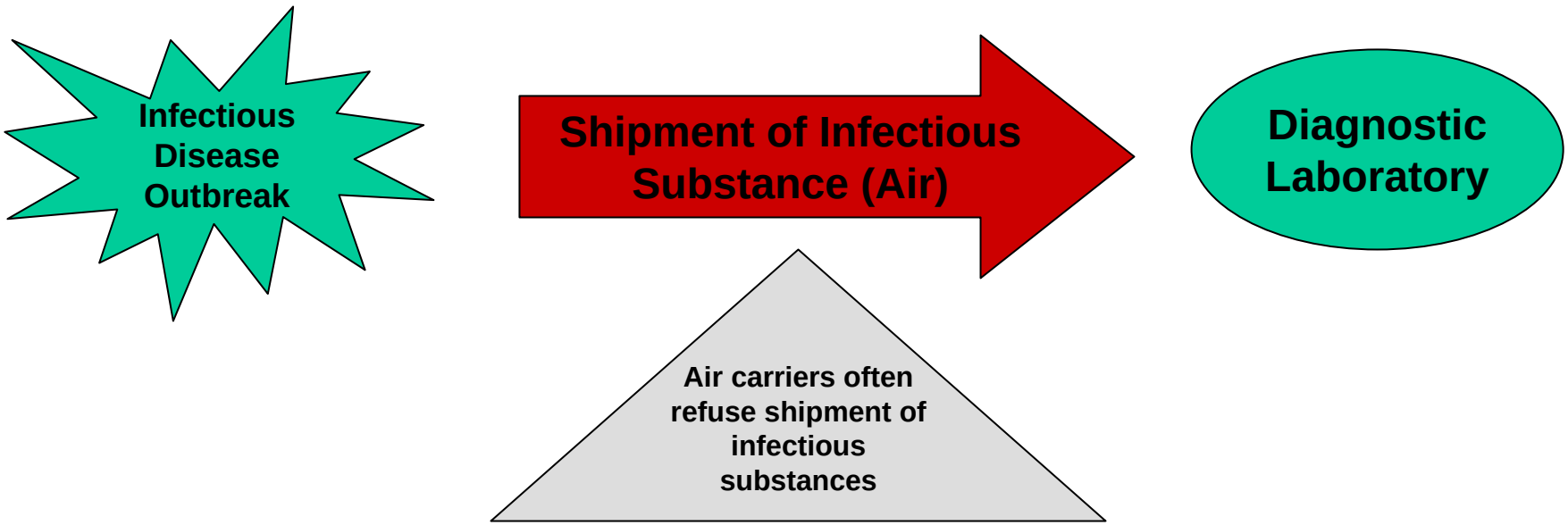
Bacillus anthracis





Coccidioides immitis

Risk Perception in Transportation



Time Delay = Increase in deaths and greater economic damage

Summary

- Many factors affect the transportation of infectious substances
  - Security becoming a more important concern issue
- UN Model regulations revised every two years
- Specific packaging requirements for international shipments
  - Category A vs Category B
- Training requirements

  - See CD for Guidelines