

# Infectious Substance Transport

*Laboratory Biosecurity and Biosafety*  
*for BSL3 Laboratories*  
**India**  
**January 2007**

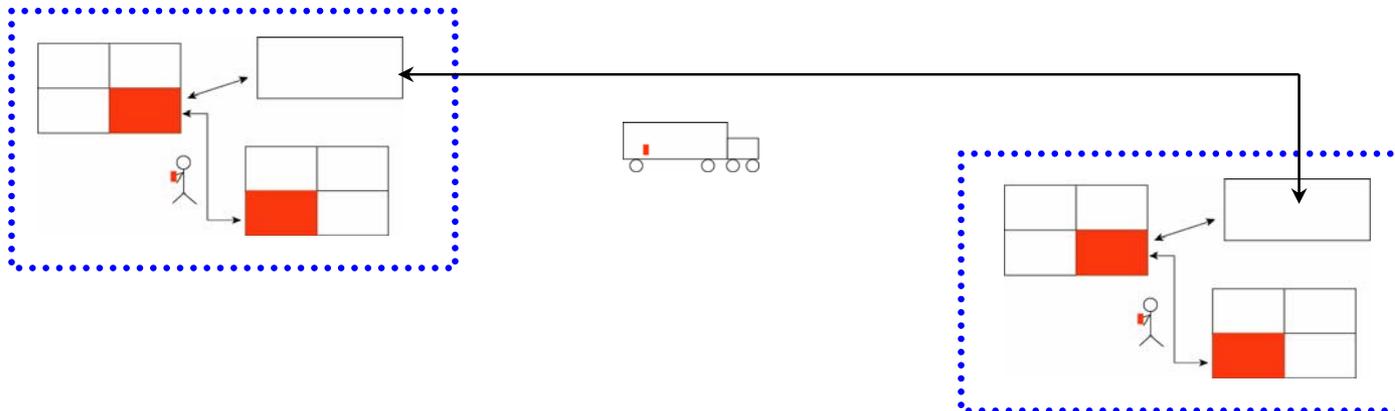
[www.biosecurity.sandia.gov](http://www.biosecurity.sandia.gov)

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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

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- **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



Model Regulations on the Transport of Dangerous Goods



ADR  
(road)

RID  
(rail)

IMO  
(sea)

ICAO  
(air)



IATA  
(air)



National Regulations



# UN Committee of Experts on Transport of Dangerous Goods

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- **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?

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- **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

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- **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

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- **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

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- **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

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<p>UN 2814 Infectious substances affecting humans</p>	<p><i>Bacillus anthracis</i> (cultures only) <i>Brucella abortus</i> (cultures only) <i>Brucella melitensis</i> (cultures only) <i>Brucella suis</i> (cultures only) <i>Burkholderia mallei</i> [<i>Pseudomonas mallei</i> – Glanders](cultures only) <i>Burkholderia pseudomallei</i> [<i>Pseudomonas pseudomallei</i>] (cultures only) <i>Chlamydia psittaci</i> [avian strains] (cultures only) <i>Clostridium botulinum</i> (cultures only) <i>Coccidioides immitis</i> (cultures only) <i>Coxiella burnetii</i> (cultures only) Crimean-Congo hemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) <i>Escherichia coli</i>, verotoxigenic (cultures only) Ebola virus Flexal virus <i>Francisella tularensis</i> (cultures only)</p>
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# Indicative examples of infectious substances included in Category A

<p><b>UN 2814</b> <b>Infectious substances affecting humans</b></p>	<p><b>Guanarito virus</b> <b>Hantaan virus</b> <b>Hanta virus pulmonary syndrome</b> <b>Hendra virus</b> <b>Hepatitis B virus (cultures only)</b> <b>Herpes B virus (cultures only)</b> <b>Human immunodeficiency virus (cultures only)</b> <b>Highly pathogenic avian influenza virus (cultures only)</b> <b>Japanese Encephalitis virus (cultures only)</b> <b>Junin virus</b> <b>Kyasanur Forest disease virus</b> <b>Lassa virus</b> <b>Machupo virus</b> <b>Marburg virus</b> <b>Monkeypox virus</b> <b><i>Mycobacterium tuberculosis</i> (cultures only)</b> <b>Nipah virus</b> <b>Omsk hemorrhagic fever virus</b></p>
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# Indicative examples of infectious substances included in Category A

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<p>UN 2814 Infectious substances affecting humans</p>	<p>Poliovirus (cultures only) Rabies virus <i>Rickettsia prowasekii</i> (cultures only) <i>Rickettsia rickettsii</i> (cultures only) Rift Valley fever virus Russian spring-summer encephalitis virus (cultures only) Sabia virus <i>Shigella dysenteriae type 1</i> (cultures only) Tick-borne encephalitis virus (cultures only) Variola virus Venezuelan equine encephalitis virus West Nile virus (cultures only) Yellow fever virus (cultures only) <i>Yersinia pestis</i> (cultures only)</p>
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# Indicative examples of infectious substances included in Category A

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<p><b>UN 2900 Infectious substances affecting animals only</b></p>	<p><b>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 <i>Mycoplasma mycoides</i> [Contagious bovine pleuropneumonia] Peste des petits ruminants virus Rinderpest virus Sheep-pox virus Goatpox virus Swine vesicular disease virus Vesicular stomatitis virus</b></p>
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# Category B Infectious Substances

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- **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**



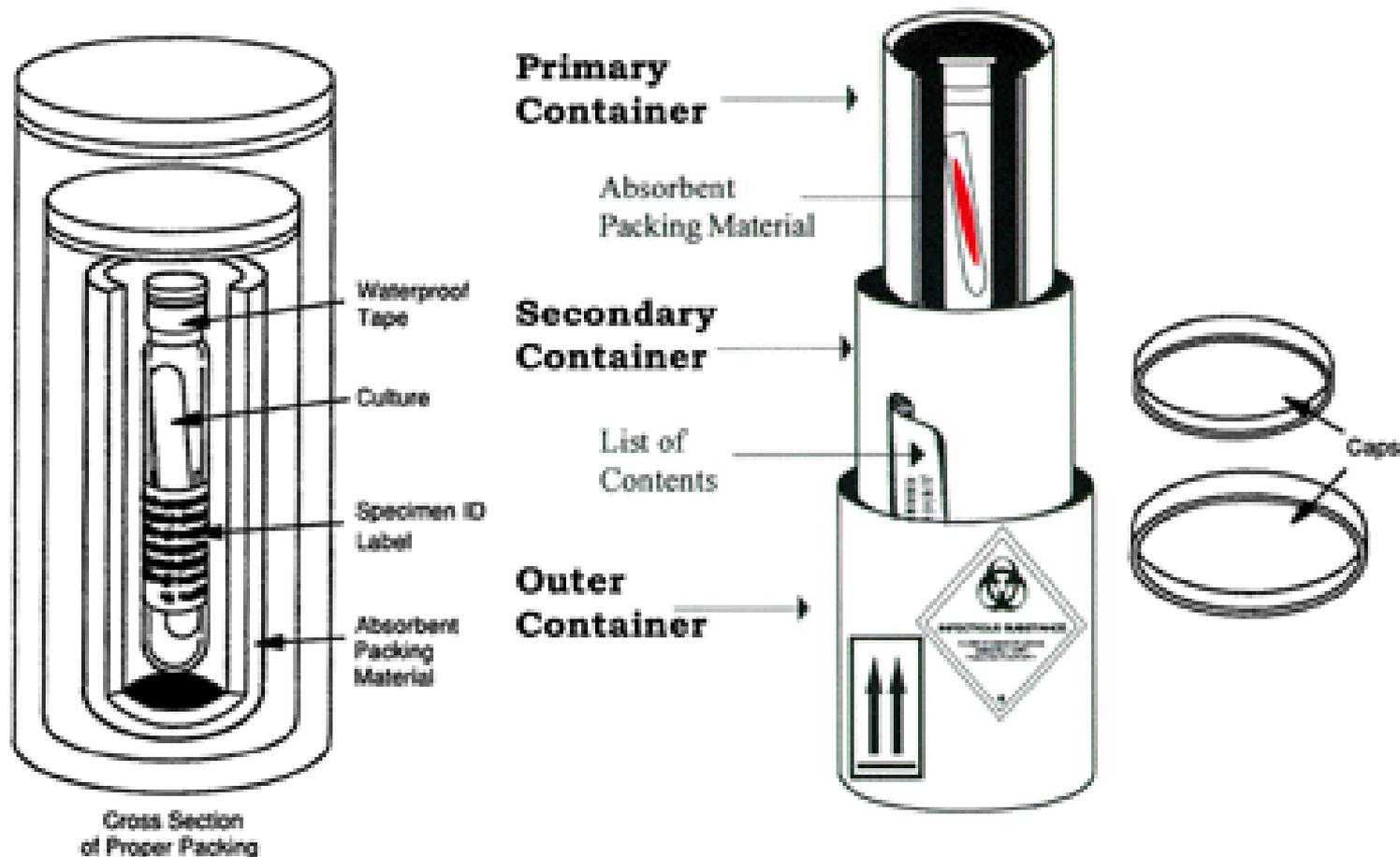
# Exemptions

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- **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!**

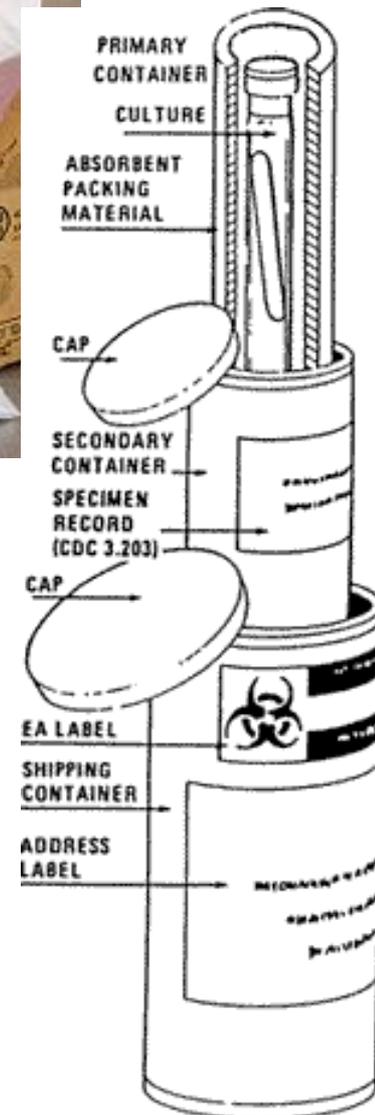


# INFECTIOUS SUBSTANCE PACKAGING



# 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**

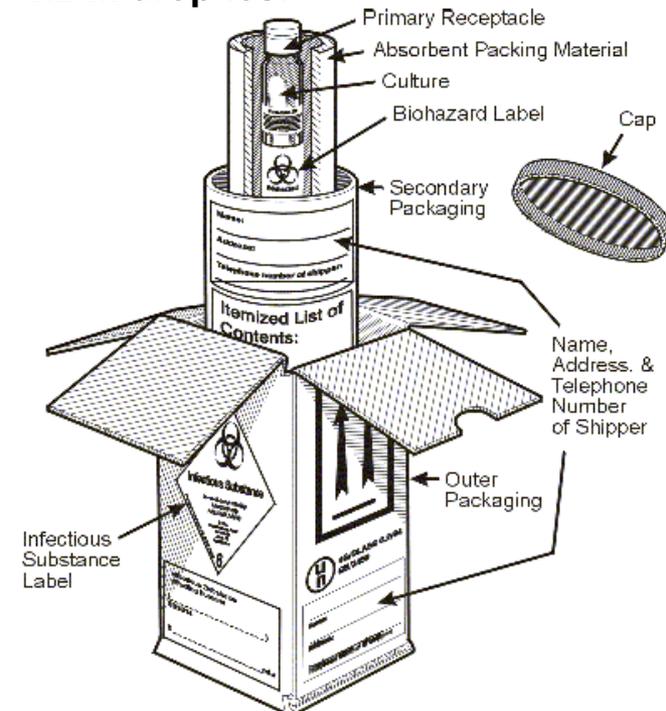
- 9 m drop test (dry, wet, 0 F, dry ice)
- Puncture test
- Stacking test
- Internal pressure test – 95 kPa

- **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)

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- **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

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- **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

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- **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

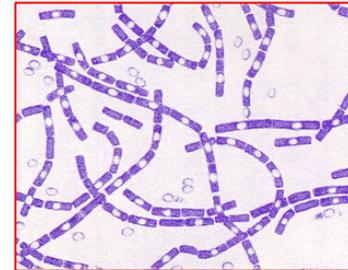
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- **Carriers should provide security by**
  - **Ensuring reliable and trustworthy people handle the package**
  - **Controlling access to transport facilities, docks, and vehicles**
  - **Tracking shipping progress**
  - **Providing ongoing security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

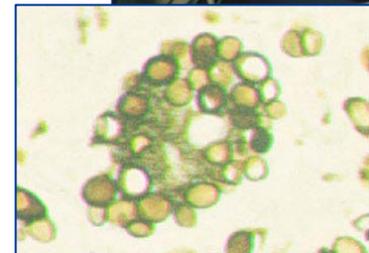
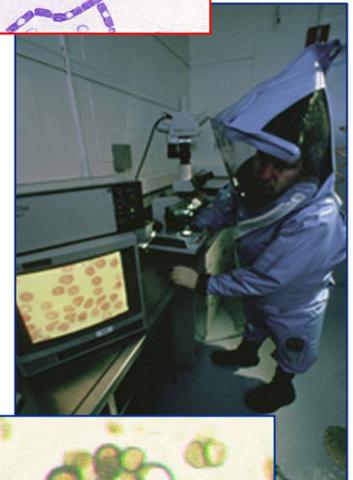


# US Requirements for Infectious Substance Transport Security

- 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*



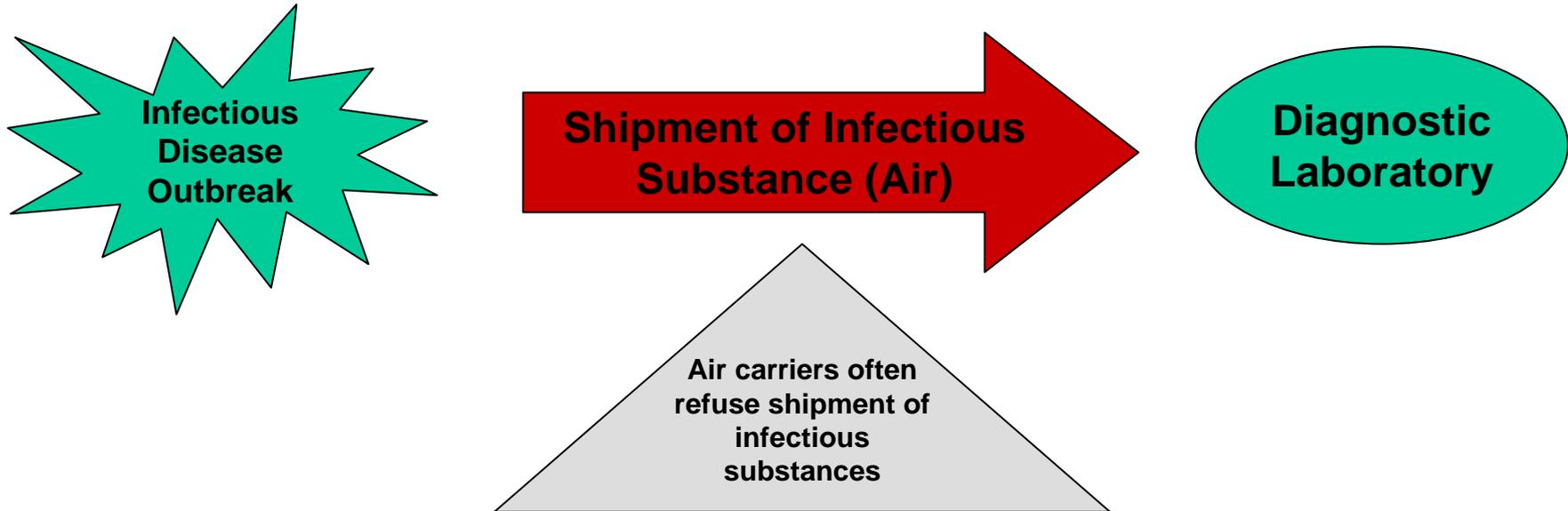
*Coccidioides immitis*



# Risk Perception in Transportation

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**Time Delay = Increase in deaths and greater economic damage**

