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# **Components of Laboratory Biosecurity – Part II**

## ***Laboratory Biosafety and Biosecurity Workshop***

**Cairo, Egypt  
3-5 April 2007**

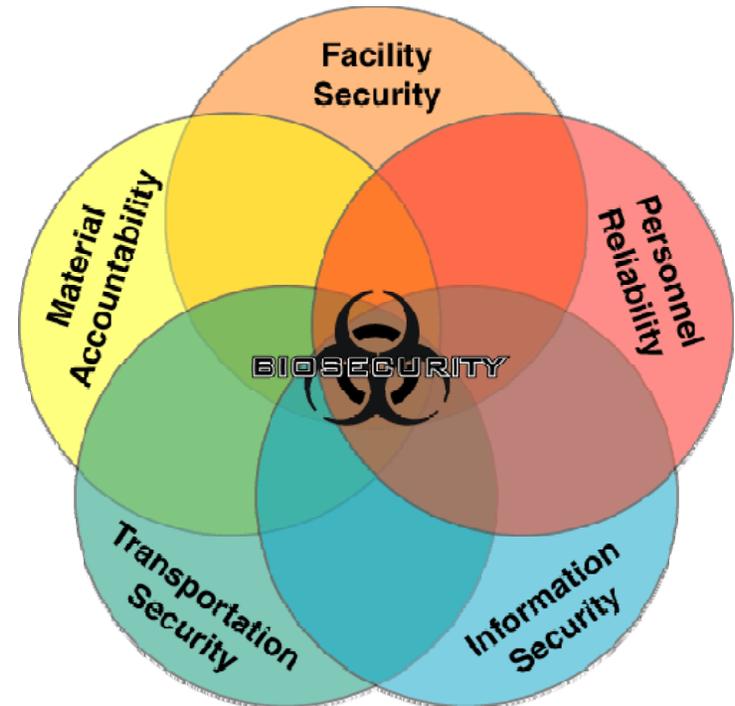
**[www.biosecurity.sandia.gov](http://www.biosecurity.sandia.gov)**

SAND No. 2005-7122C

Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,  
for the United States Department of Energy's National Nuclear Security Administration  
under contract DE-AC04-94AL85000.

# Biosecurity System

- **Biosecurity system components**
  - Physical security
  - Personnel security
  - Material handling and control measures
  - Transport security
  - Information security
  - Program management practices
- **Each component implemented based on results of risk assessment**
- **In general, biosecurity for**
  - Moderate risk focuses on the insider
  - High risk focuses on both the insider and the outsider



# Material Control & Accountability: Objective

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- **Ensure the complete and timely knowledge of:**
  - What materials exist
  - Where the materials are
  - Who is accountable for them
- **NOT: to detect whether something is missing**

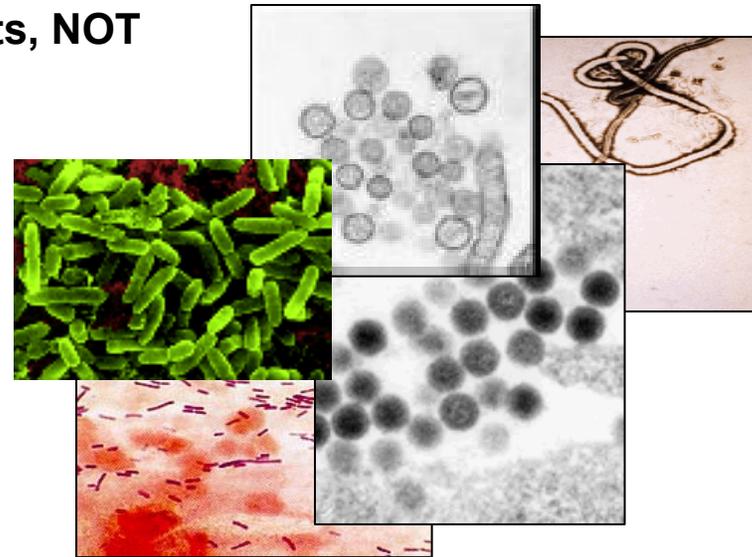
# Material Control & Accountability: Key Issues

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- **What materials are subject to MC&A measures**
- **The operating procedures associated with the materials**
  - where they can be stored and used
  - how they are identified
  - how inventory is maintained
- **What records need to be kept for those materials and the timeliness requirements for those records**
- **What does accountability means**
- **Documentation and reporting requirements**

# Material Control and Accountability

- Defining “material” is complicated
- Agent
  - Name and description
- Quantity
  - Based on containers or other units, NOT number of microbes



# Material Control and Accountability

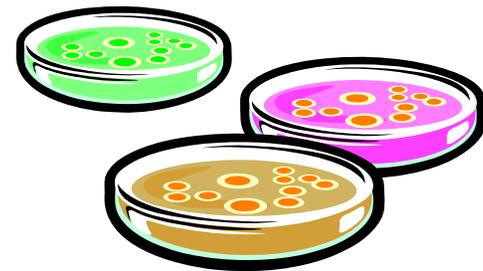
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- **Agent**
  - What agents are high risk?
  - Viable? Whole organism or DNA?
- **Quantity**
  - Any amount can be significant
  - A threshold amount for toxins
- **Form**
  - Repository stocks, working samples, in host, contamination
- **Detail—what level is adequate for MC&A?**
  - Material as *items*
  - Each vial as a separate inventory record?
- **Capture—when does MC&A start & stop?**
  - Naturally occurring; clinical samples; disposition

# Material Control and Accountability

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- **Attributes:** to characterize the material (“what”)
  - Agent / strain
  - Origin
  - Date
- **Description:** to identify a particular *item* of the material (“which”)
  - Container
  - Identification
  - Location

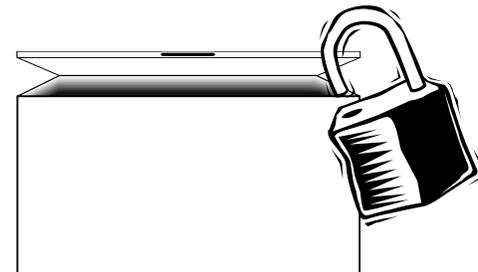
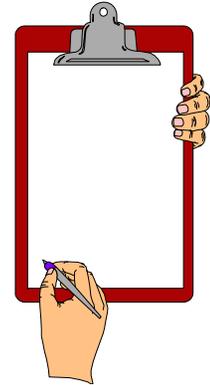


# Material Control and Accountability

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- **Control is either...**
  - Engineered / Physical
  - Administrative
- **Containment is part of material control**
  - Containment Lab / Freezer / Ampoule
- **Procedures are essential for material control**
  - For both normal and abnormal conditions

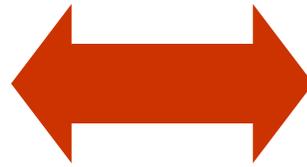
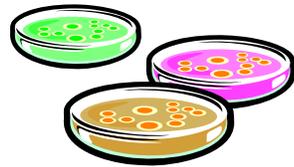


# Material Control and Accountability

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- All material should have an associated “accountable person”
  - The person best in a position to answer questions about the associated material
  - Not someone to blame!
  - Ensure that no material is “orphaned”



# Material Control and Accountability

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- **Procedures should ensure accountability**
  - **Experimental work: laboratory procedures**
  - **Inventory: know what you have**
  - **Reporting: document routine MC&A practices**
  - **Audit/ assessment: is this working?**
    - Ensures effective *implementation* of MC&A
  - **Training: personnel understand requirements**

# Material Control & Accountability

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**Much of MC&A is likely already done for reasons other than biosecurity...**

- **Biosafety**
- **Good research practice**
- **Business interest**

# Material Control & Accountability

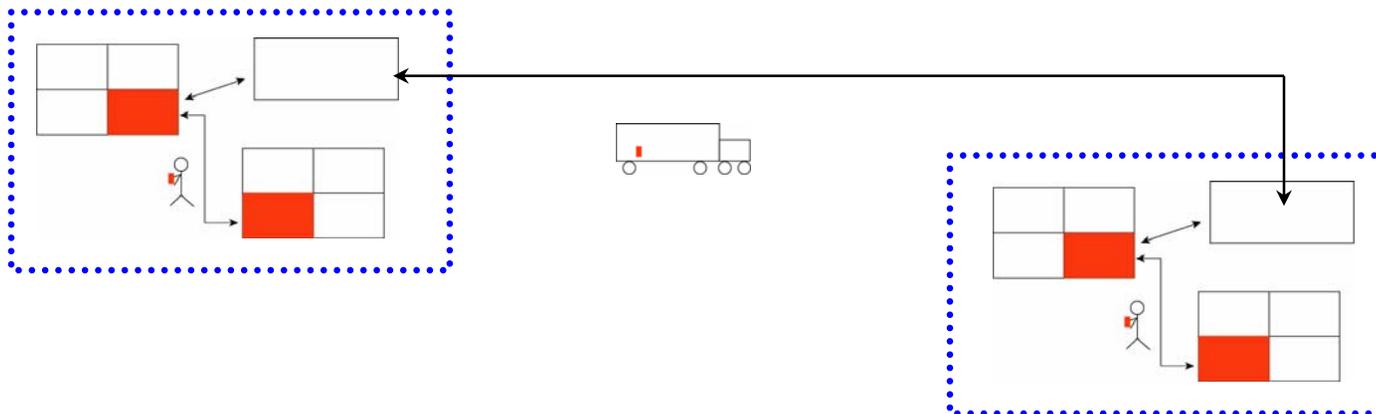
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- **Moderate**
  - **Seed stocks cataloged and records stored securely**
    - Transfers in and out
    - Source
    - Strain
    - Form
    - Responsible individual
  - **Working stocks, including infected animal status, tracked through laboratory notebooks**
  
- **High**
  - **Moderate plus**
    - Increased control over working stocks



# 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

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- **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)

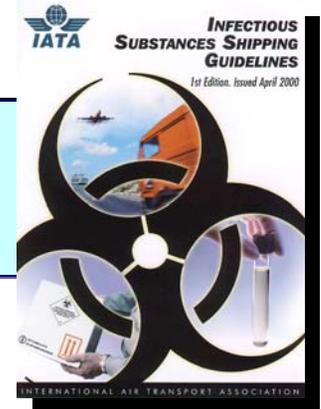
IMO  
(sea)

ICAO  
(air)



IATA  
(air)

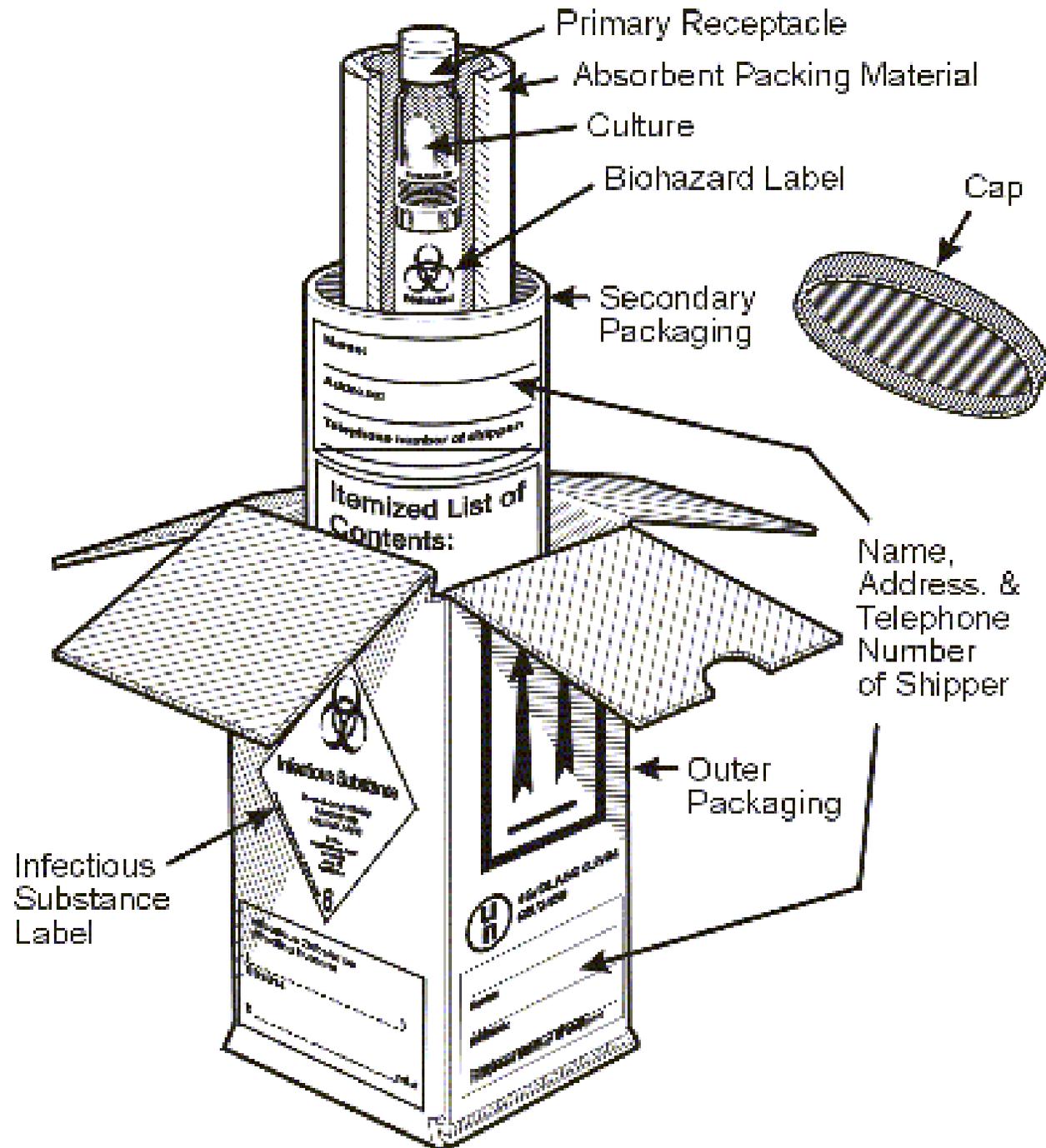
National Regulations



# 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



# 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



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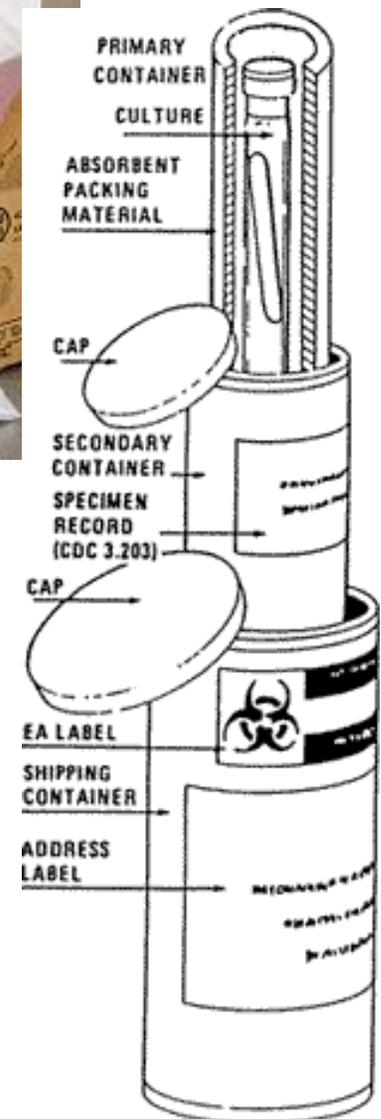
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- **Blood or blood products for transfusion**
- **Tissues or organs for transplant**
- **Materials with low probability of containing infectious substances (foodstuffs, water samples, living persons)**
- **However, WHO recommends that all specimens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



# 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
    - 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

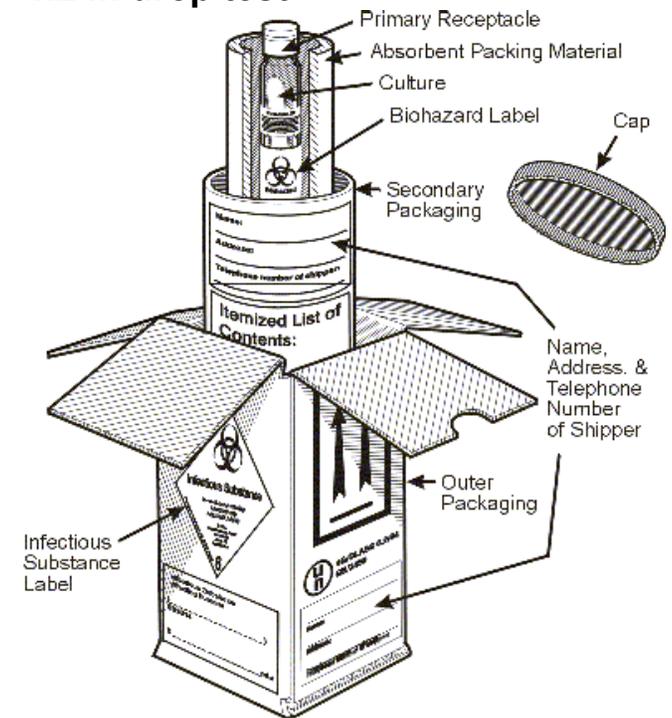
- **Category B Infectious Substances (650)**

- **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**



# Transport Security

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- **Moderate**
  - Internal transport personnel screened
  - Recipient screened for legitimacy
  - Safe receipt notification
  
- **High**
  - **Moderate plus**
    - Chain of custody
    - Physical controls on storage containers

# Components of Biosecurity

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