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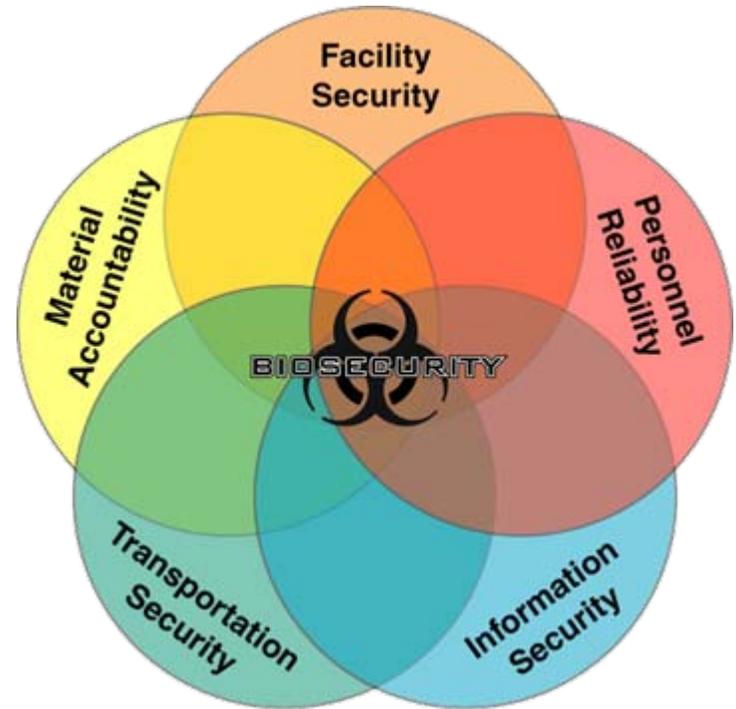
# *Components of Biosecurity II*

**Sandia National Laboratories**  
***Laboratory Biosecurity and Biosafety Workshop***  
**Pune, India**  
**4 May 2006**

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

# 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**

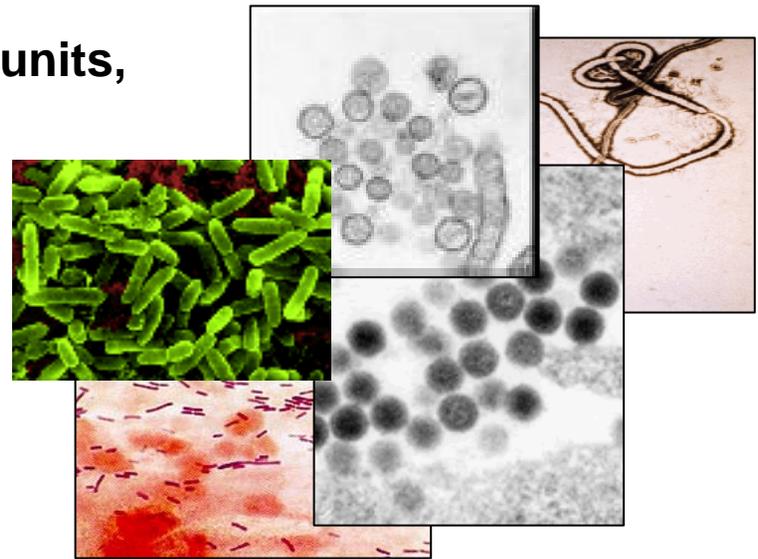
# Material Control & Accountability: Key Issues

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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

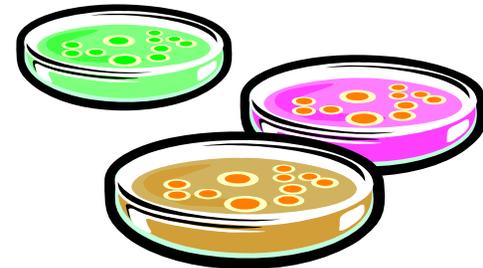
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- **Agent**
  - What agents are high risk?
  - Viable? Whole organism or DNA?
- **Quantity**
  - Any amount can be significant
  - A threshold amount for toxins
- **Form**
  - Repository stocks, working samples, in host, contamination
- **Detail—what 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

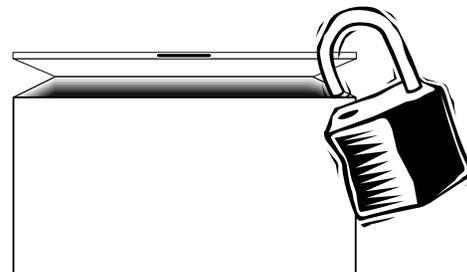
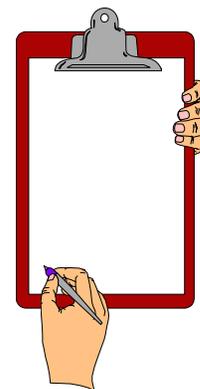
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- **Attributes:** to characterize the material (“what”)
  - Agent / strain
  - Origin
  - Date
  
- **Description:** to identify a particular *item* of the material (“which”)
  - Container
  - Identification
  - Location



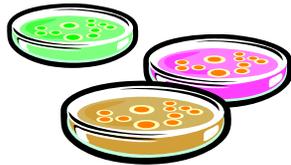
# Material Control and Accountability

- **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

- 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

- **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



# Material Transport Security

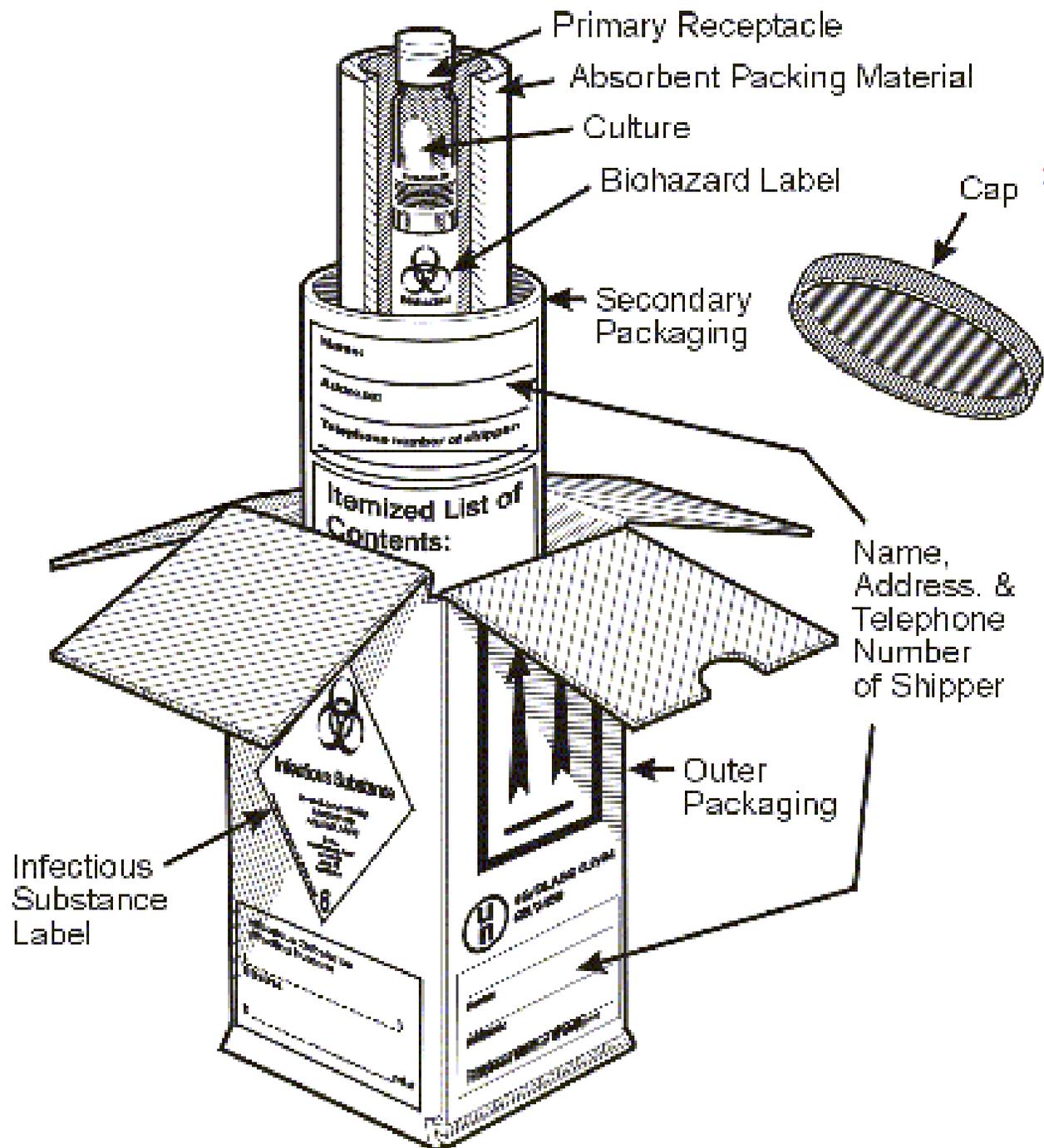
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- **Transport – movement of biological material outside of a restricted area**
  - **Research labs**
    - Sample transfers are necessary for study and to further research
  - **Public health labs and diagnostic labs**
    - Sample transfers are necessary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

# International Transport Regulations

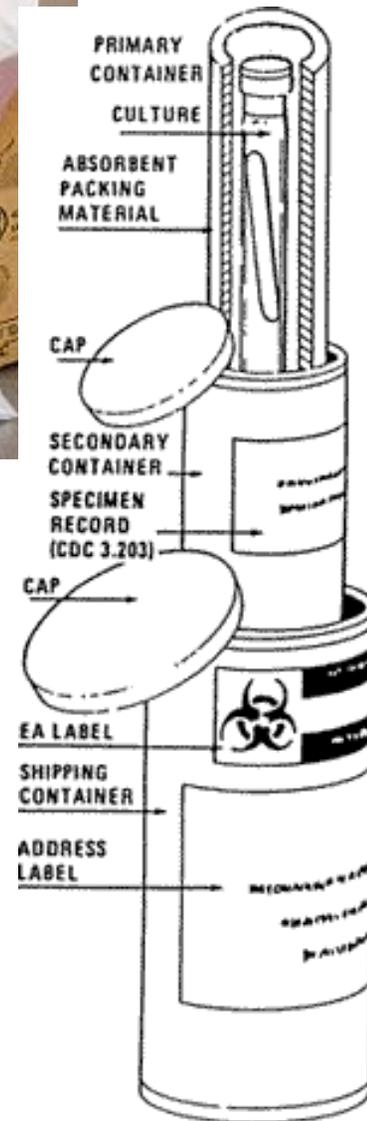
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- **UN Committee of Experts on Transport of Dangerous Goods**
  - 27 countries (voting)
  - Non-voting observers
    - ICAO, IATA, WHO, ....
  - Model Regulations (Orange Book)
- **Modes of Transportation**
  - International Civil Aviation Authority (ICAO)
  - Others: Road, Rail, Air
- **National Regulations**



# Shipping of Infectious Materials

- **Permit to Ship**
  - **Classify material**
    - Infectious vs diagnostic
- **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**
    - Section 9 Hazmat
    - 6 lbs. For 48 hours



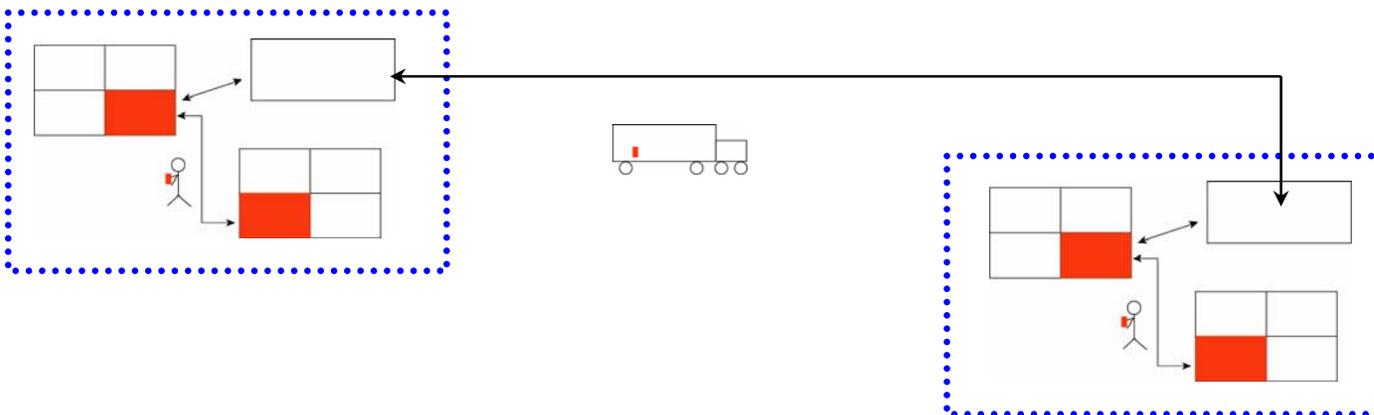
# Packaging

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- **Infectious substance (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
- **Diagnostic specimen (650)**
  - **Non-specification package**
    - Leak-proof primary
    - Secondary packaging
    - Outer packaging
  - **Tests**
    - 1.2 m drop test

# Material Transport Security

- **Why?**
  - Dangerous pathogens and toxins are vulnerable to theft during movement outside of protected areas
- **Who?**
  - Facilities, carriers, and states all responsible
- **The goal of transport security is**
  - To mitigate the risk of theft during transport



# 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)**

# 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**



# Transport Security: Chain of Custody

- **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: Need for Balance

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- **Transport security mechanisms must be balanced with the need to:**
  - **Comply with transport safety regulations**
  - **Move frozen materials efficiently**
  - **Remain cost-effective**

# 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

