



Transfer Security

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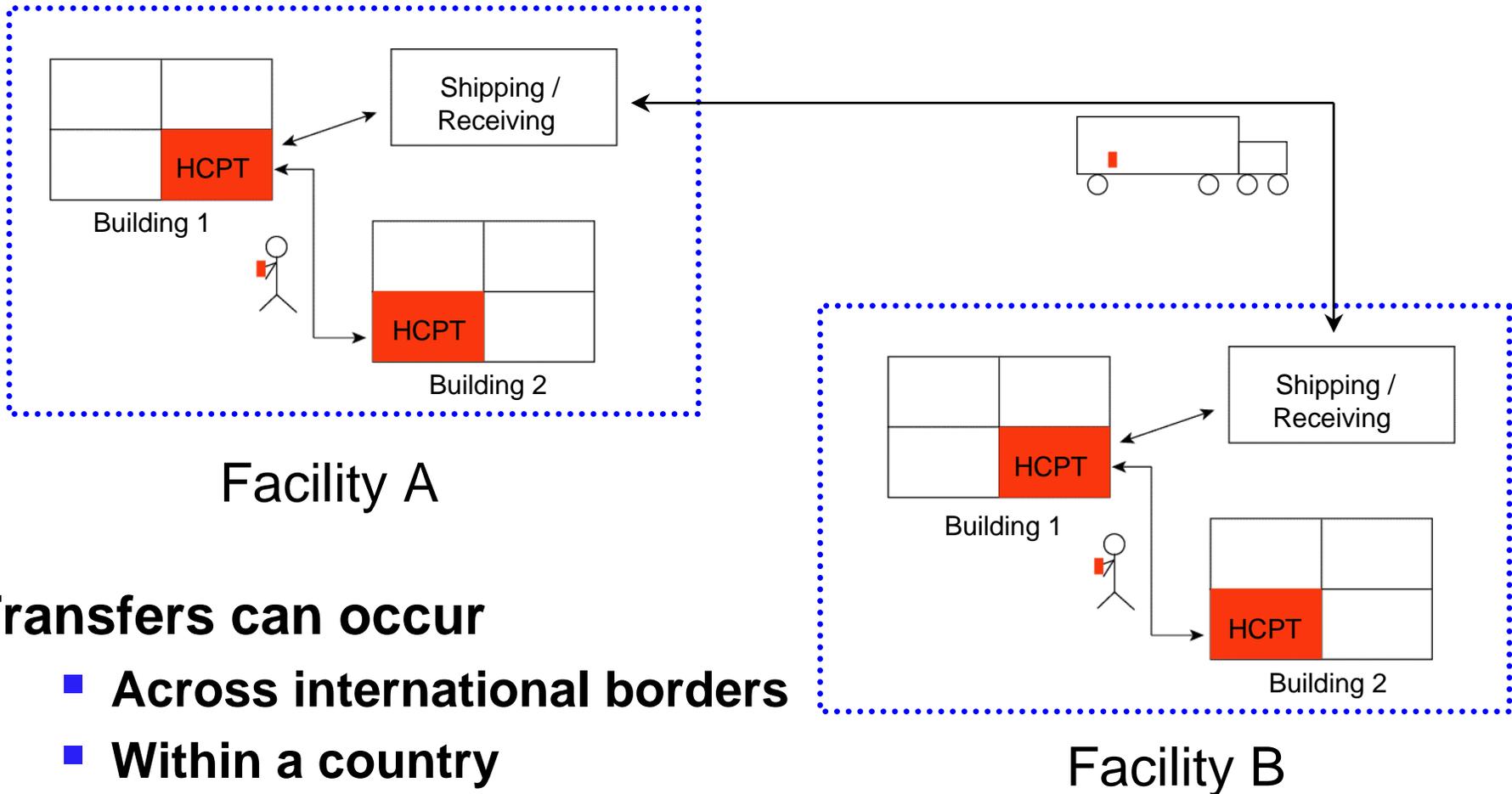


Biological Material Transfers

- **Transfer – 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**



Biological Material Transfers



Facility A

Facility B

Transfers can occur

- Across international borders
- Within a country
- Within a facility



Material Transfer Security

- **Why?**
 - **High Consequence Pathogens and Toxins (HCPTs) are vulnerable to theft during movement outside of protected areas**
- **Who?**
 - **Facilities, carriers, and states all responsible**
- **The goal of transfer security is**
 - **To mitigate the risk of theft during transfer**

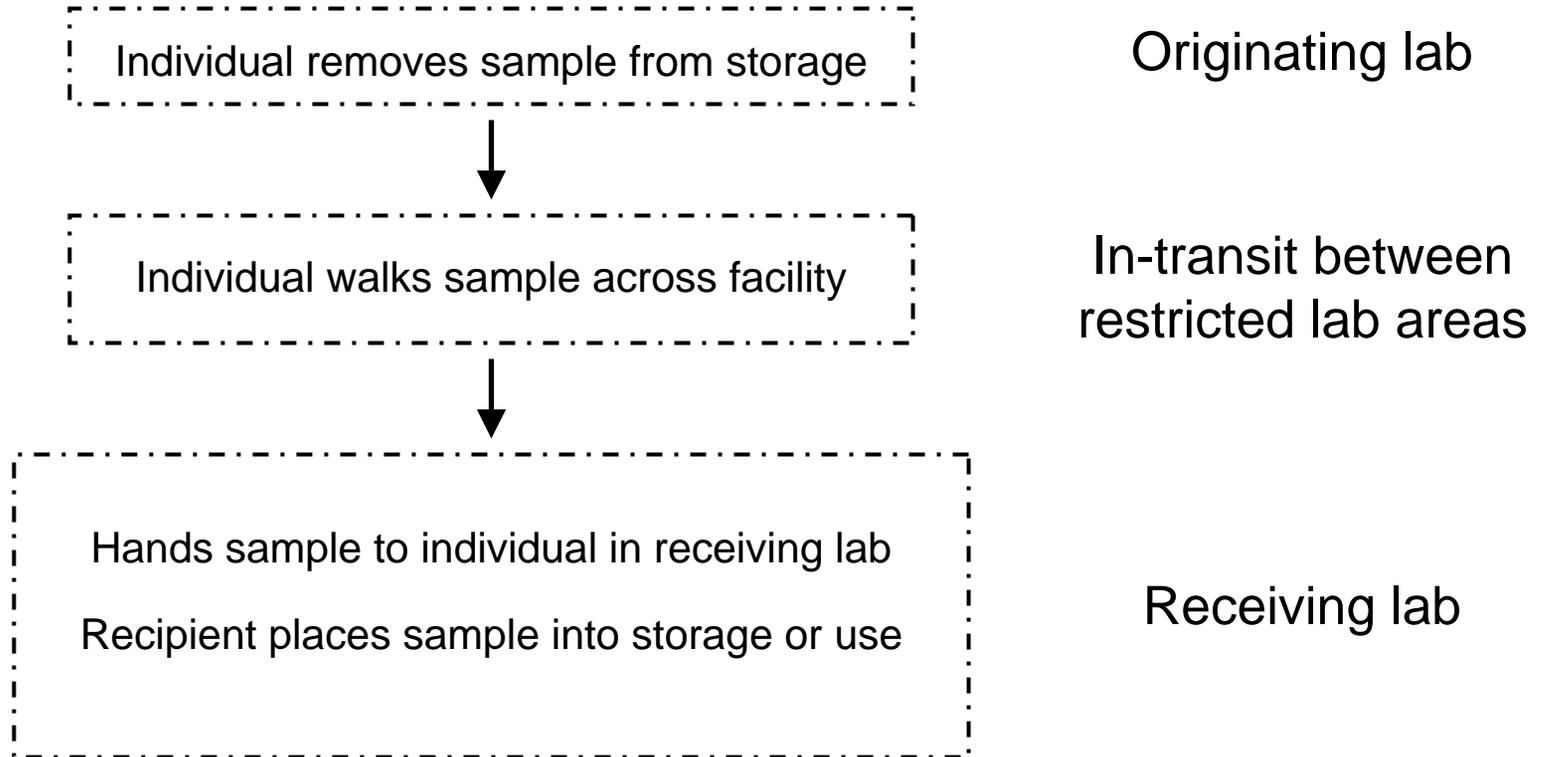


Internal Transfers

- **Movement of HCPTs 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)**

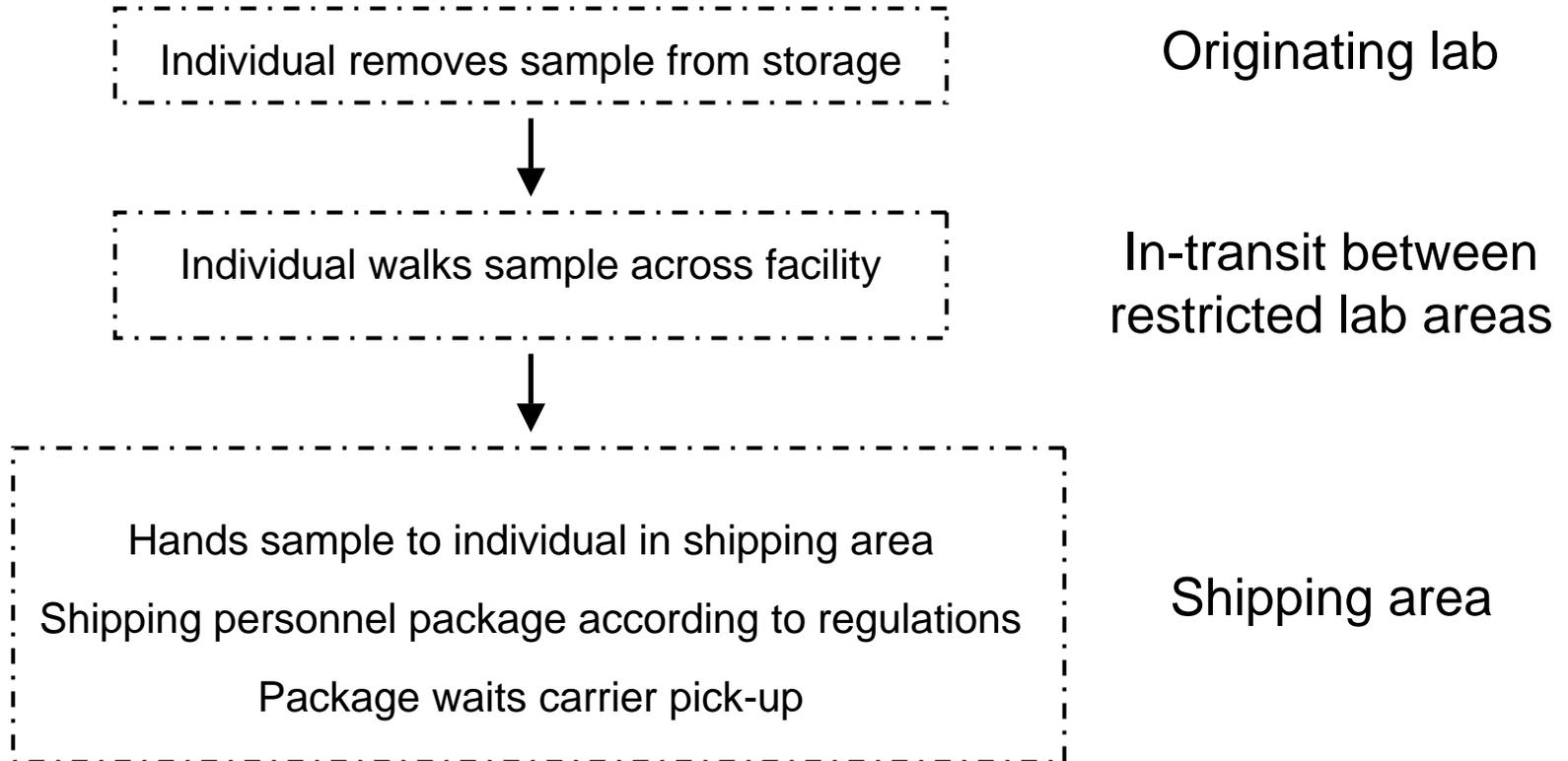


Typical Internal Transfers: Example 1





Typical Internal Transfers: Example 2





The New Reality: Facility Responsibilities

- **Personnel suitability**
 - **For people who have access to HCPTs or information during transfers**

- **Establish chain of custody (CoC)**
 - **Record all individuals who have contact with the HCPT**

- **Provide physical security**
 - **For packages that need temporary storage**

- **Protect transfer documentation**

- **Determine who is able to authorize, transfer, and receive HCPTs**



Chain of Custody: Principles

- **Aims to protect integrity of 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
 - Space to document individual assuming custody on behalf of someone else



Chain of Custody: Implementation

- **Electronic example**



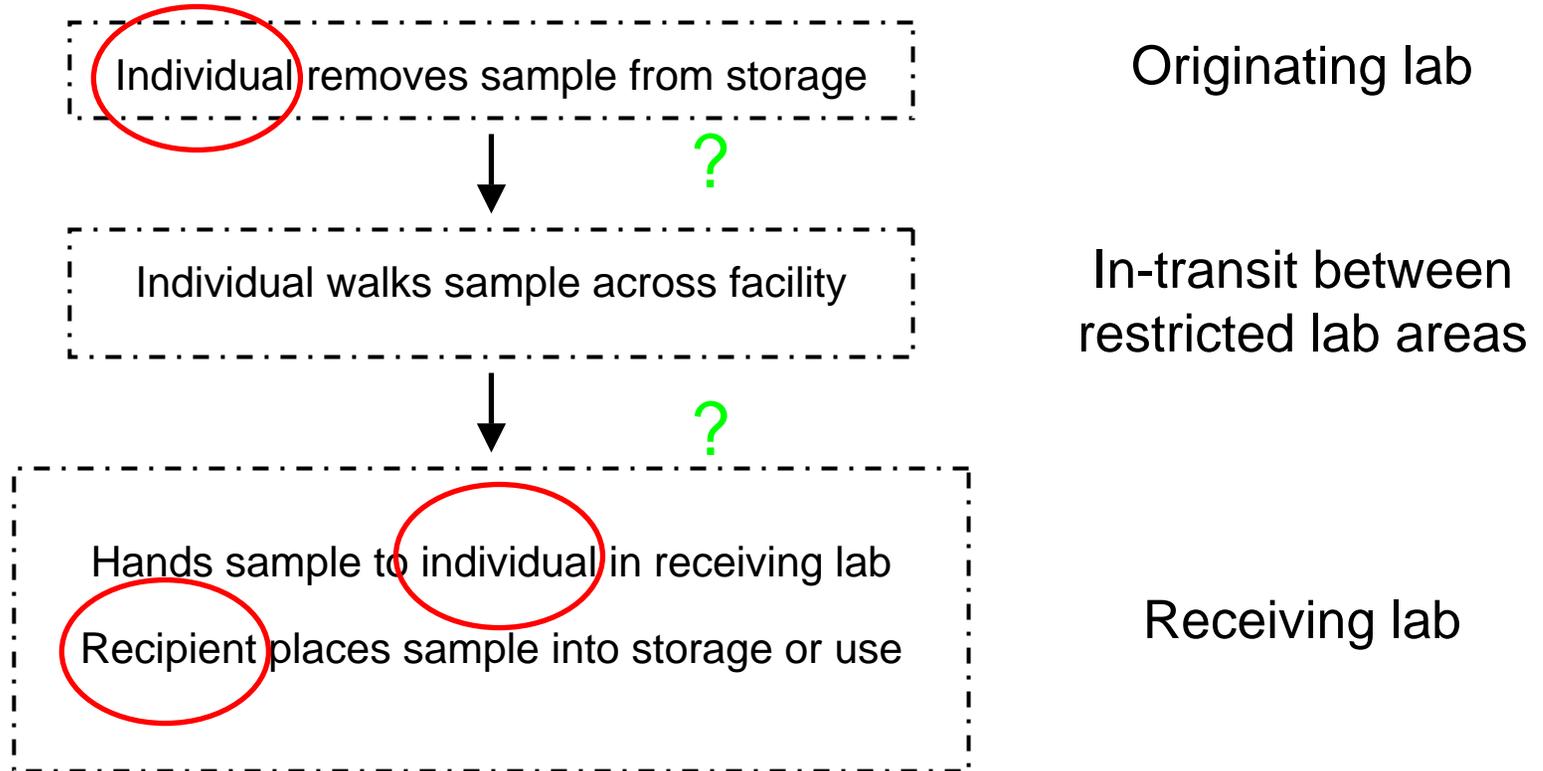
- **Paper example**

Chain of Custody for Internal Transfers

Description of Biological Material:			
Responsible Person:		Name	Phone/Email
time/date	Recipient signature	Transferrer signature	Notes



Typical Internal Transfers – What's missing?

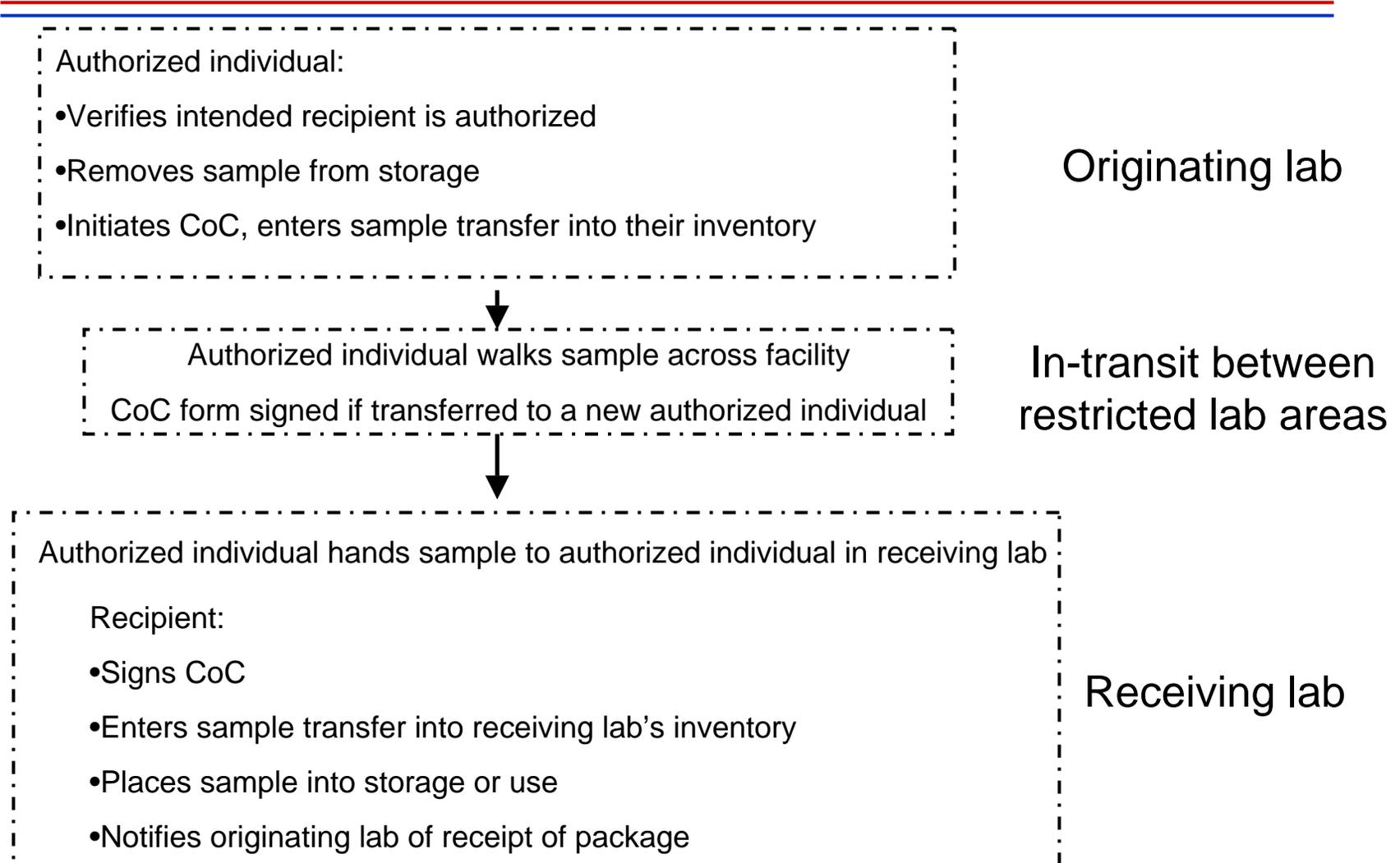


Personnel suitability

Documentation, Chain of Custody



Best Practices: Internal Transfers





External Transfers

- **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**

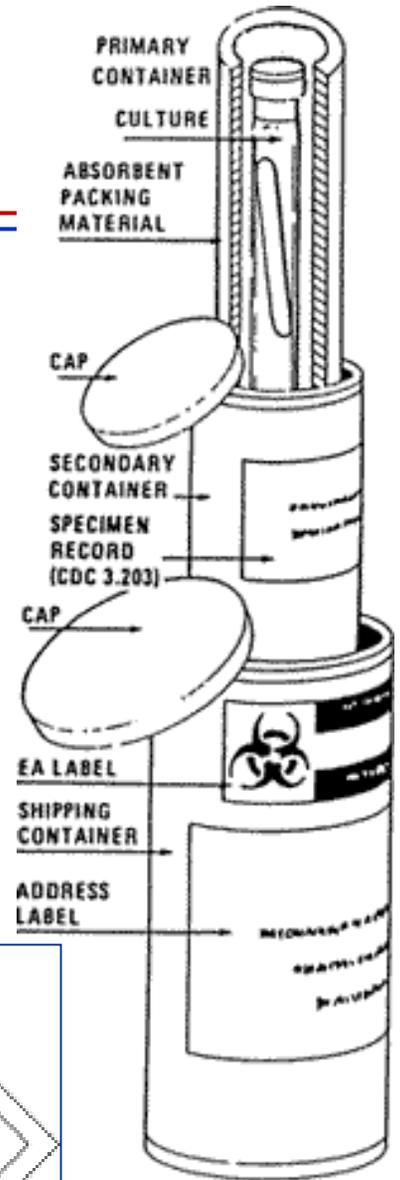




International Shipping Standards

- **Packaging, labeling, and marking standards address biosafety concerns**
 - UN Committee of Experts on the Transport of Dangerous Goods
 - World Health Organization (WHO)
 - International Civil Aviation Organization (ICAO)
 - International Air Transport Association (IATA)
 - Universal Postal Unions (UPU)

- **Opportunity for security collaboration**





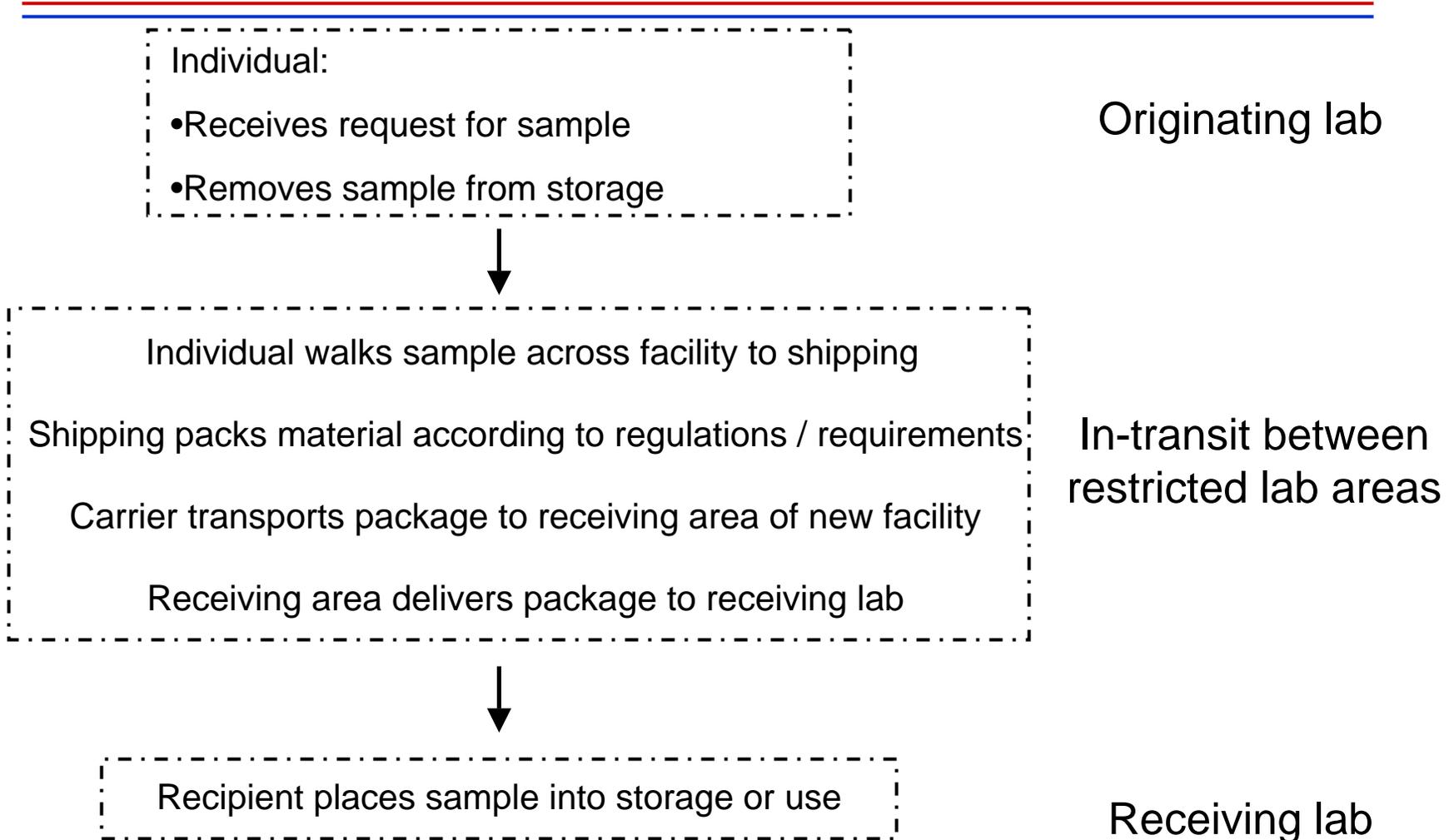
Carrier Security

- **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**





Typical External Transfers





Enhancing Security of External Transfers

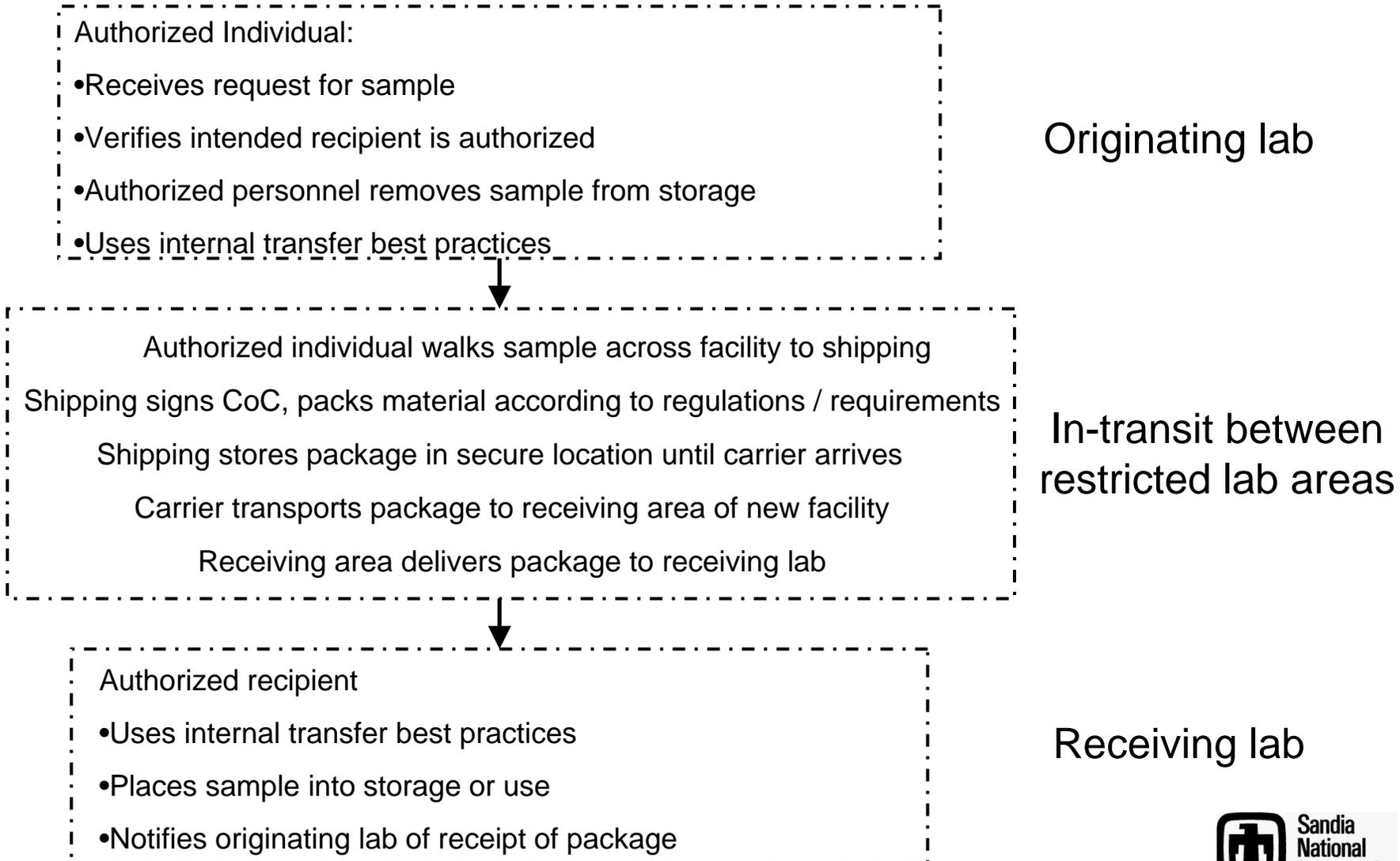
- **Use of timely (overnight) shipping methods to minimize exposure to shipping system**

- **Oversight**
 - **Registration program**
 - **To track facilities and people working with HCPTs**
 - **Limits transfers to those between registered facilities**
 - **Keeps a record of transfers**

- **Documentation and accountability**
 - **Originating and receiving labs keep transfer records**
 - **End-use agreement:**
 - **Authorized user**
 - **Governs how recipient can further transfer the HCPT**



Best Practices: External Transfers





Transfer Security: Need for Balance

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



Summary

- **Transfers are essential for research and public health**
- **Transfer security can be enhanced through the following mechanisms:**
 - **Control**
 - **Accountability**
 - **Documentation**
 - **Oversight / authorization / audits**
 - **Personnel reliability**