



Wisconsin State
Laboratory of Hygiene

UNIVERSITY OF WISCONSIN-MADISON

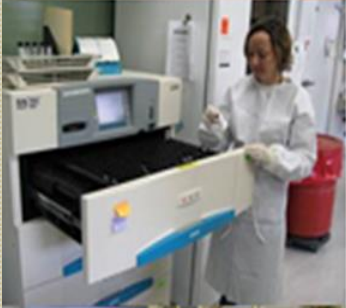
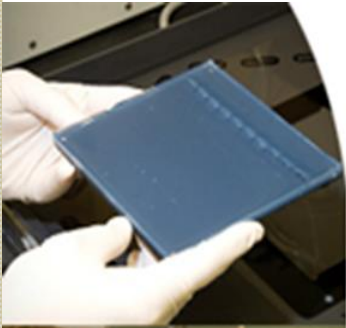


What is Packaging and Shipping Certification and Why is it Important?

December 16, 2015

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Disclaimer

This presentation **Does Not substitute or meet the requirements for Packaging and Shipping training.**



Objectives

- Explain how compliance with packaging and shipping regulations improves the culture of laboratory biosafety.
- Discuss who regulates the packaging and shipping of infectious substances and why.
- Describe the training components and documentation required for packaging and shipping certification.



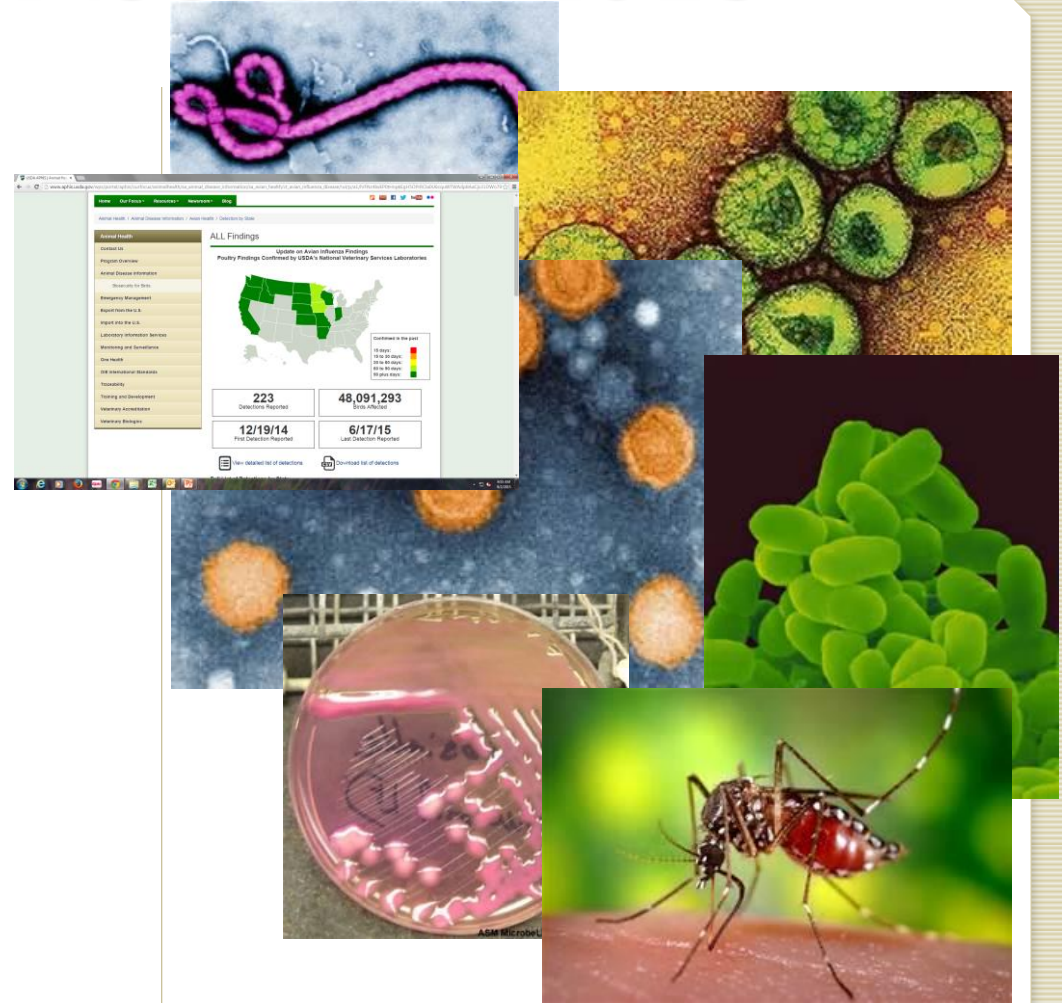
Why Does Your Laboratory Need to Make Sure You Certify Staff Who Package and Ship Hazardous Materials in Packaging and Shipping?





The Ongoing Threat of Emerging Infectious Diseases - 2015

- **Ebola virus**
- EV-D68
- MERS CoV
- Influenza
 - HPAI (H5NX)
 - H5N1, H7N9
- Anthrax
- Tularemia, Brucella
- Dengue fever
- Chikungunya





EVD Cases (United States)

- EVD has been diagnosed in the United States in four people, one (the index patient) who traveled to Dallas, Texas from Liberia, two healthcare workers who cared for the index patient, and one medical aid worker who traveled to New York City from Guinea
 - **Index patient** – Symptoms developed on September 24, 2014 approximately four days after arrival, sought medical care at Texas Health Presbyterian Hospital of Dallas on September 26, was admitted to hospital on September 28, testing confirmed EVD on **September 30**, patient died October 8.
 - **TX Healthcare Worker, Case 2** – Cared for index patient, was self-monitoring and presented to hospital reporting low-grade fever, diagnosed with EVD on **October 10**, recovered and released from NIH Clinical Center October 24.
 - **TX Healthcare Worker, Case 3** – Cared for index patient, was self-monitoring and reported low-grade fever, diagnosed with EVD on **October 15**, recovered and released from Emory University Hospital in Atlanta October 28.
 - **NY Medical Aid Worker, Case 4** – Worked with Ebola patients in Guinea, was self-monitoring and reported fever, diagnosed with EVD on **October 24**, recovered and released from Bellevue Hospital in New York City November 11.

Information on U.S. EVD cases available at <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html>.



Are We Prepared to Respond to Public Health Threats from a Biosafety Perspective?





Ebola: Impacts in the Laboratory

Ebola (Ebola Virus Disease)

CDC > Ebola (Ebola Virus Disease) > U.S. Healthcare Workers and Settings

Laboratories


Recommend Tweet Share

Language: English

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- [Specimen Collection, Transport, and Submission](#)
- [Packing and Shipping Specimens](#)
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Managing and Testing Routine Clinical Specimens




[Managing and Testing Routine Clinical Specimens](#)

Specimen Collection, Transport, and Submission



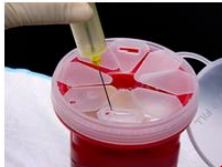
[Specimen Collection, Transport, and Submission](#)

Packing and Shipping Specimens



[Packing and Shipping Specimens](#)

Waste Management



[Waste Management](#)

U.S. Preparedness and Procedures

- [Preparing for Ebola - A Tiered Approach](#)
- [Personal Protective Equipment \(PPE\)](#)
- [Evaluating Patients](#)
- [Cleaning and Disinfecting](#)

U.S. Settings

- [Emergency Services](#)
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- [Outpatient Settings](#)
- [Information for Laboratories](#)

International (Non U.S.) Settings

- [Breastfeeding](#)
- [Hand Hygiene](#)
- [Risk of Transmission](#)
- [Training for West Africa](#)

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Biosafety Headlines! All is Not Well in the Lab

**Latest military lab concerns involve plague bacteria,
deadly viruses**

Tom Vanden Brook and Alison Young, USA TODAY 3:31 p.m. EDT September 10, 2015

It's 10 o'Clock -- Do You Know Where Your Bubonic Plague Is?

Spilled smallpox, missing SARS, and rogue scientists with mutant H1N1. If you're not scared, you should be.

BY LAURIE GARRETT

**Smallpox find was among hundreds of
other long-lost vials, FDA says**

By LAUREN RAAB, July 16, 2014

Anthrax scare reveals more CDC lab safety problems

*By Associated Press
July 11, 2014*

**After Lapses, C.D.C. Admits a Lax
Culture at Labs**

*By RICHARD FAUSSET and DONALD G. MCNEAL Jr.,
JULY 13, 2014*

Pentagon: Poor testing led to Army shipping live anthrax

Alison Young and Tom Vanden Brook, USA TODAY 7:42 p.m. EDT July 23, 2015

**Frieden Testifies At Hearing On
CDC Lab Safety Lapses**

CBS Evening News 7/16/14



USA Today: Taking Aim at Laboratories

<http://www.usatoday.com/topic/9ee9e5de-b702-4fbc-9e5d-1b595adcf938/biolabs/>

Biolabs

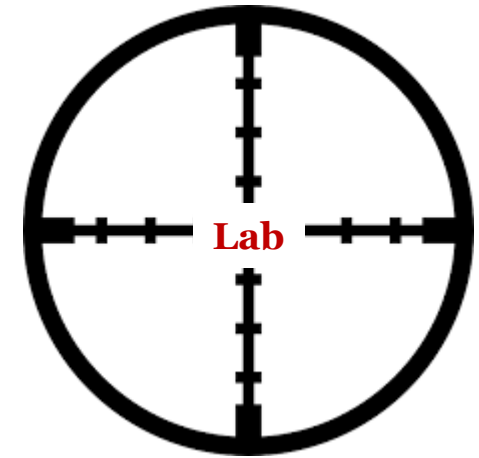
Inside America's secretive biolabs
A USA TODAY NETWORK INVESTIGATION

Universities: feds fight to keep lab failings secret

CAUTION!
10 incidents discovered at the nation's biolabs

HEADLINES

- Smallpox: Fda hiring top official to improve lab safety in wake of smallpox incident
- Amber alert: Scientists just threw out test tube showing sample was alive
- CDC hires top lab safety official to address string of incidents, culture
- GRIP: Market-building lab concerns involve plague bacteria, deadly viruses
- Pentagon talks work with bioerror germs at 9 labs
- US biolabs for infectious disease research with bioerror germs
- Secret sanctions revealed against university hosting \$1.25 billion biolab
- FedEx no longer to transport bioerror germs in wake of anthrax lab mishaps
- Congress questions oversight of biolab safety at hearing
- CDC lacked key lab incident reporting policy despite scrutiny, promises
- Pentagon: Poor testing led to Army shipping live anthrax
- CDC to review oversight of bioerror labs after USA TODAY investigation





APHL Position Statement: Improving Biosafety in Our Nation's Laboratories

*"The **Association of Public Health Laboratories** and **CDC** supports the enhancement of biosafety practices in the nation's laboratories through :*

- ***development of consensus standards,***
- ***improved reporting of exposure events,***
- ***identification of true risk and best practices,***
- ***implementing routine risk assessments and standardized training"***

-April 2015-



Epidemiology and Laboratory Capacity (ELC) Funding: 2015-2017

- Domestic Ebola supplemental funding opportunity for public health
- Funding objective:
 - To enhance laboratory biosafety and biosecurity capacity at the WSLH.
 - To support clinical labs to assess, develop and implement measures to improve laboratory biological safety practices for dealing with current and emerging infectious diseases.
- Funding covers a 3 year project



Lab Safety Begins With Risk Assessment

- Assess biological risks
 - Identify hazards
 - Consider the agent, the host, and the environment
 - Estimate risk based on likelihood and severity of the occurrence...**based on work being performed**
- Risk mitigation and exposure avoidance
 - Identify and implement controls and work practices
- Monitor effectiveness
 - Review all accidents, exposures and near misses
 - Review effectiveness of control measures
 - Identify training needs
 - Modify procedures



What should the Risk Assessment Cover?

- **Pre-analytical activities** from the time the specimen is collected, transported, unpackaged, centrifuged, aliquoted, and moves through the lab
- **Analytical activities**
- **Post-analytical activities** including clean up of lab and equipment, destruction of the specimen and lab-generated materials, storage of specimens and cultures, **and packaging and shipment**



ELC Funding: 2015-2017

Additional Activities

- **Provide training** on biosafety/biosecurity related topics.
 - Packaging and shipping training
 - Biosafety/biosecurity best practices
- **Maintain a library** of links to biosafety/biosecurity resources on our “WCLN Resources” webpage: <http://www.slh.wisc.edu/wcln-surveillance/wcln/wcln-resources/>
- **Conduct drills/exercises** to determine competency in select areas of biosafety/biosecurity.
 - Packaging and shipping drills



ELC Funding: 2015-2017

Performance Measures

- Every 6 months WSLH completes CDC mandated performance measures and participates in a conference call to give a progress report.
- The ELC *Standard for shipping*

Data Element		October 2015
1	Total number of sentinel clinical laboratories in the jurisdiction. See additional guidance. (n can range from 0 to 9,999) (Denominator)	
1.a	Of this number, how many are part of Ebola Treatment Centers (ETC) or Ebola Assessment Hospitals (EAH) in your jurisdiction (n=0 to 9,999)?	
2	Number of sentinel clinical labs in which at least two staff members are currently certified in safe packaging/shipping of International Air Transport Association (IATA) Division 6.2 infectious substances (Category A) (n=0 to 9,999) (Numerator)	
2.a	Of this number, how many are part of ETC or EAH in your jurisdiction (n=0 to 9,999)?	



Additional Activities

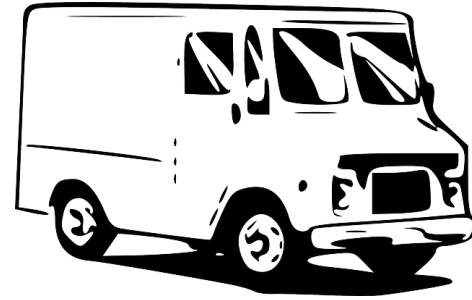
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Regulatory Overview

Modes of Transport:

- Ground
 - Motor Vehicle
- Air
 - Passenger aircraft
 - Cargo aircraft
- US Mail
 - Air mail
 - First class postage
 - Priority and Priority Express





Regulatory Agencies

Department of Transportation (DOT)



- <http://www.phmsa.dot.gov/hazmat>
- Hazardous Material INFO LINE 1-800-467-4922
- **Regulate:**
 - Air (allowance to use international guidelines)
 - Ground
 - Water (cannot be used for 6.2 hazardous materials transport)
- **Regulation:**
 - *Hazardous Materials Regulations* (HMR) - free
 - 49 Code of Federal Regulations (CFR)
 - 49 CFR Parts 171-177



DOT Revisions

<http://www.phmsa.dot.gov/pipeline/regs/rulemaking>

- Occur as needed
- Issued for comment
 - Notice of public rulemaking
 - Advanced notice of public rulemaking
- Posted on website

The screenshot shows the PHMSA Rulemaking page. The header includes the PHMSA logo, U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration, and a search bar. The main content area is titled 'Rulemaking' and contains a list of rulemaking actions. The list includes the following items:

Rulemaking ID	Rulemaking Description	Effective Date
80 FR 63310	Pipeline Safety: Safety of Hazardous Liquid Pipelines.	Oct 13, 2015
80 CFR 43826	Pipeline Safety: Pipeline Damage Prevention Programs. Action: Final Rule.	Jul 23, 2015
REV NRM PHMSA-2011-0009	Expanding the Use of Excess Flow Valves in Gas Distribution Systems to Applications Other Than Single Family Residences.	Jul 15, 2015
80 FR 29916	Pipeline Safety: Operator Qualification, Cost Recovery, Accidents and Incident Notification, and Other Pipeline Safety Proposed Changes.	Jul 10, 2015
PHMSA NRM - Accident Notification-02 June 2015	Pipeline Safety: Operator Qualification, Cost Recovery, Accidents and Incident Notification, and Other Pipeline Safety Proposed Changes.	Jun 29, 2015
80 FR 23262	Pipeline Safety: Issues Related to the Use of Plastic Pipe in the Gas Pipeline Industry. Action: NRM.	May 21, 2015
80 FR 12762	Pipeline Safety: Miscellaneous Changes to Pipeline Safety Regulations. Action: Final Rule.	Mar 11, 2015
80 CFR 168	Pipeline Safety: Periodic Update of Regulatory References to Technical Standards and Miscellaneous Updates. Action: Final Rule.	Jan 5, 2015
78 FR 59206	PHMSA has received two requests to extend the comment period to allow stakeholders more time to evaluate the notice of inquiry. Action: NRM.	Sep 30, 2013
78 FR 58997	Pipeline Safety: Update the administrative civil penalty maximums. ACTION: Final rule.	Sep 25, 2013
78 FR 49926	Pipeline Safety: Periodic Updates of Regulatory References to Technical Standards and Miscellaneous Amendments. Action: NRM.	Aug 14, 2013
78 FR 46749	Pipeline Safety: Class Location.	Aug 1, 2013



DOT Penalties

CFR 49, Section 171.1, (g)

- ***Penalties for noncompliance.***

Each person who knowingly violates a requirement of the Federal hazardous material transportation law, an order issued under Federal hazardous material transportation law, subchapter A of this chapter, or a special permit or approval issued under subchapter A or C of this chapter is liable for a civil penalty of not more than \$75,000 for each violation, except the maximum civil penalty is \$175,000 if the violation results in death, serious illness or severe injury to any person or substantial destruction of property. There is no minimum civil penalty, except for a minimum civil penalty of \$450 for a violation relating to training.



Regulatory Agencies

Occupational Health and Safety Administration (OSHA)



- <http://www.osha.gov>
- **Regulate:**
 - Provide minimal packaging and labeling requirements for human blood and body fluids when transported within a laboratory or outside of it.
- **Regulation:**
 - *29 CFR Part 1910.1030 - Free*



Guidance Agencies



US Postal Service (USPS)

- <http://pe.usps.com/text/pub52/welcome.htm>
- **Provide guidance for:**
 - USPS Air mail
 - USPS Surface transport (6.2 hazardous materials not allowed)
- **Guidance:**
 - *Publication 52 – Hazardous, Restricted, and Perishable Mail – Free*
 - *Postal Bulletin*
 - Issued monthly and posted on website



Guidance Agencies

International Civil Aviation Organization (ICAO)



- <http://www.icao.int>
- **Guidance:**
 - *Technical Instructions for the Safe Transport of Dangerous Goods by Air (Technical Instructions)*
 - Issued every 2 years and must be purchased



Guidance Agencies

International Air Transport Association (IATA)



- **Provides guidance for:**
 - Member airlines, including FedEx and UPS
- **Guidance:**
 - *Dangerous Goods Regulations (DGR)*
 - Published yearly and must be purchased
 - <http://www.iata.org/publications/Pages/index.aspx>
 - Revisions (addenda) posted when issued on website
 - For free addendum to the DGR listing significant changes and other free materials.
 - <http://www.iata.org/whatwedo/cargo/dgr/Pages/download.aspx>



What is Packaging and Shipping Certification?

- **It is the training component required by the DOT, USPS, and IATA of anyone who affects the transport of hazardous materials.**
 - **DOT:** *"A hazmat employer shall ensure that each of its hazmat employees is trained in accordance with the requirements."*
 - **IATA:** *"The successful application of rules concerning the transport of dangerous goods greatly depends on the appreciation by all professionals of the risks involved. Training is key to achieve a detailed understanding of the Regulations."*



Training Requirements

If individual packages and ships Category A or ships specimens by air using > 5.5 lbs. per package of dry ice:

- To become certified in packaging and shipping an individual must have documented training and competency in the following:
 - General awareness/familiarization training:
 - Provides training to familiarize employee with the regulations
 - Identifies hazardous materials
 - Function specific training:
 - Must provide detailed training in the requirements applicable to the job for which the employee is responsible
 - Safety training:
 - Must cover the hazards presented by 6.2 infectious substance hazmat, how to safely handle 6.2 hazmat and emergency response procedures required when packaging and shipping
 - Security awareness training:
 - Provides awareness of security risks,



Training Requirements

If an individual packages and ships Category A and works in a facility that possesses select agents, there is an additional requirement for:

- In-depth security training:
 - See the DOT Security Brochure (free)
http://www.phmsa.dot.gov/pv_obj_cache/pv_obj_id_D9751A8FDE298BFC643B65B52B45975E67586400/filename/Enhanced%20Security%20Brochure.pdf
 - Select agent security training



Training Requirements

If an individual packages and ships only Category B:

- Training:
 - Must be knowledgeable of the packaging instructions
 - Manufacturer must provide packaging instructions with the package
 - Maintain copies of instructions a minimum of 1 year
 - No competency testing is required
 - Documentation
 - Not required by DOT
 - Is required by CAP
 - IATA guidance suggests familiarization with the regulations and understanding of classification



Training Frequency

- **Requirements differ slightly among regulatory and guidance agencies**
- Initial training:
 - Complete within 90 days of hire or change of job function
 - Prior training is acceptable
- Recurrent (refresher) training:
 - Every 3 years
 - DOT and accrediting agencies (CAP & Joint Commission)
 - Every 2 years
 - IATA
 - If Security plan is revised must be retrained in 90 days



P&S Training Providers

- **WSLH/APHL** – Bring in a trainer for a full day of training every other year – last provided May 2015
 - JBM Associates, Inc., — Patricia Payne (in-person training only) – 859-608-3143
- **CDC Train** – online training suitable for initial and refresher training
 - <https://cdc.train.org/DesktopShell.aspx>
- **Saf-T-Pak** — online training
 - <http://www.saftpak.com/Training/training.aspx>
- **HighQ, LLC.** —
 - <http://www.highqllc.com/>



Certified Shipper's Responsibilities

Must be knowledgeable of and comply with the regulations for any or all of the following functions you perform:

- Identification of hazmat
- Classification
- Packaging
- Marking
- Labeling
- Documentation

LRN recommends having at least 2 individuals certified in packaging and shipping



Classification

- **Both DOT and IATA/USPS provide Classification charts**
 - Must use the appropriate classification chart for the mode of transportation you are using
 - Classification charts similar, but slightly different
- **Both DOT and IATA provide Category A Indicative Lists**
 - List isn't inclusive of all possibilities
 - Must use risk assessment and judgement when sending unknown organism isolates
 - Suspect Category A Infectious Substance affecting humans



Packaging

- Triple packaging required for Category A, Category B, and Exempt human or animal specimens
- Category A primary container must be taped or parafilmmed shut if a screw cap container
- If shipping Category A or B liquid specimens by air, IATA requires that any biohazard bags used as the primary or secondary package must be able to withstand a 95 kPA pressure differential
- Secondary packaging contains cushioning material if multiple or fragile specimens and absorbent if specimen is liquid
- OSHA requires a biohazard label be affixed to the primary or secondary packaging on all human blood specimens or other potentially infectious material.
 - USPS requires the biohazard label to be affixed to the inner packaging
- Must include an itemized list of content within the outer packaging for Category A specimens
- Outer container must be rigid for Category A and B specimens



Labels and Markings

Category B:

- Outer package must be labeled UN3373 Biological substance, category B
- Responsible person information includes:
 - Name of individual - responsible for providing information to mitigate an incident
 - Phone number - answered during normal business hours

Category A:

- Outer package must be labeled UN2814 Infectious substance affecting humans or UN2900 Infectious substance affecting animals
- Outer container must have UN specification rating UN 4G/CLASS 6.2 marking and package must be used as a unit without substitution of components
- Emergency contact information includes:
 - Name of individual – knowledge about the package
 - Phone number – must be answered by a person the entire time the specimen is in transit



Shipper's Declaration

- Required for Category A packages
 - IATA calls Dangerous Goods Form
 - DOT calls Shippers Declaration
- Contact transporter to find out if they require a specific form
 - FedEx requires use of their on-line software
- Make 3 copies
 - Shipper keeps a copy for minimum of 2 years
 - Must be readily accessible
 - Transporter keeps a copy
 - Receiver keeps a copy
- Include written emergency response information
 - May be attached as a separate document such as a MSDS sheet



Competency Assessment

- Employer provided written test
- Employer observation
- Drills and exercises
 - CDC developing Virtual P&S Exercise
 - APHL/State Training Coordinator working with DOT to obtain special permit to conduct Category A exercises
 - Paper drills



Employer's Responsibilities

Certification is granted and documentation is maintained by the employer as follows:

- Provides or verifies prior training
- Provides or verifies prior testing and assesses current competency
- Creates and signs certification document
- Maintains training records
 - Employee name
 - Date of training – beginning with the most recent and inclusive of the past 3 years
 - Training materials – keep copy of, or describe material, or document the location where kept
 - Name & Address of Trainer
 - Maintain most current training record throughout employment plus 90 days
 - Records must be accessible for inspection



New WSLH Courier Service

New courier service is Statmedex

- Service is provided free of charge by the WSLH CDD for approved emergency response, outbreak detection, and WSLH requested surveillance specimens and by NBS for newborn screening cards
- Service is by request only – no standing pick-ups
- Service can be requested through use of on-line software, or by telephone
- New service allows both the sender and the WSLH to track packages
- Courier will transport Category A and B packages – will reject specimens not packaged properly
 - For Category A use DOT Shipper's Declaration found on WCLN Resources webpage at: <http://www.slh.wisc.edu/wcln-surveillance/wcln/wcln-resources/>



Summary

- Certification in Packaging and Shipping is not a choice, but is required by federal regulation for all facilities that ship known or suspect Category A, 6.2 Infectious Substances.
- Packaging and Shipping compliance is mandatory for achieving a culture of laboratory biosafety.
- You need to know who your courier is and how they transport your packages because that determines what regulations/guidance you must follow to competently and safely package and ship a specimen.

