Category A Packaging and Shipping Drill

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Idaho Bureau of Laboratories
Outline

• Idaho Bureau of Laboratories (IBL) Overview
• Ebola Supplemental Grants
• Lab Safety Outreach Workshop
• 2016 Category A Packaging and Shipping Drill
• Next Steps
IBL Overview
Idaho’s Statistics
- 39th in population: 1.6 million residents
- 14th in total area: 83,570 square miles
- 44 counties
- Distance by car of major cities from Boise
  - Coeur d’Alene – 378 miles
  - Lewiston – 267 miles
  - Nampa – 29 miles
  - Twin Falls – 128 miles
  - Pocatello – 237 miles
  - Idaho Falls – 256 miles

Idaho’s 7 Public Health Districts

<table>
<thead>
<tr>
<th>District</th>
<th>Health District</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Panhandle</td>
<td>phd1.idaho.gov</td>
</tr>
<tr>
<td>2</td>
<td>North Central</td>
<td>idahopublichealth.com</td>
</tr>
<tr>
<td>3</td>
<td>Southwest</td>
<td>publichealthidaho.com</td>
</tr>
<tr>
<td>4</td>
<td>Central</td>
<td>cdhd.idaho.gov</td>
</tr>
<tr>
<td>5</td>
<td>South Central</td>
<td>phd5.idaho.gov</td>
</tr>
<tr>
<td>6</td>
<td>Southeastern</td>
<td>siphidaho.org</td>
</tr>
<tr>
<td>7</td>
<td>Eastern</td>
<td>idaho.gov/phd7</td>
</tr>
</tbody>
</table>

- Deliver local public health services
- Work closely with state and local agencies
- Each district has a board of health appointed by county commissioners.
IBL’s Place in Government

Other Departments include:
- Administration
- Agriculture
- Correction
- Environmental Quality
- Fish & Game
- Labor

Governor C.L. “Butch” Otter

Health & Welfare

Medicaid
Family and Community Services
Behavioral Health
Public Health
Licensing and Certification
Welfare (Self-Reliance)
Operational Services
IT

Business Operations
Clinical and Preventive Services
Community and Environmental Health
EMS and Preparedness
Laboratories
Communicable Disease Prevention
Vital Records and Health Statistics
Rural Health and Primary Care

Departments
Divisions
Bureaus
NLTC 9
National Laboratory Training Conference

IBL Organization

Bureau Chief

Lab Support
- Building Facilities
- LIMS
- Quality Management
- Safety/Security

Business Operations
- Administrative Support
- Budget & Grant Management
- Shipping & Receiving

Chemistry
- Certification
- Chemical Threat (LRN-C)
- Inorganics
- Organics
- Air Filter Testing

Clinical
- Mycobacteriology
- Serology
- Virology

Microbiology
- Certification
- Biological Threat (LRN-B)
- Environmental Microbiology
- Molecular Epidemiology
- Reference Bacteriology

Laboratory Improvement
- Air and Water Quality Audits
- CLIA Program
- Developmental Science
- X-Ray Program
NLTC 9
National Laboratory Training Conference

IBL Statistics

• 20,000 square feet laboratory space
• Biosafety Level 3 suite of labs (select agents, TB)
• 38 full-time employees
• ~ 60,000 samples per year
  ◦ 72% Microbiology
  ◦ 26% Environmental
  ◦ 2% Biological/Chemical Threats
IBL Mission

As the only public health laboratory in Idaho, IBL provides laboratory services to support the programs within Idaho’s Department of Health and Welfare, seven Public Health Districts, other state agencies, and private customers.

TESTING
- Communicable disease agents in clinical specimens
- Contaminants or adulterants in water, food, and soil
- Biological and chemical threats

INSPECTION
- Clinical and environmental laboratories
- X-ray and mammography units
- Air quality monitoring stations

TRAINING
- Consultation and workforce development
- Continuing education seminars and telelectures
- Scientific presentations at local, regional, and national meetings

OUTREACH
- Development and evaluation of new analytical methods
- Publication of applied public health research
- Maintenance of the Idaho Sentinel Laboratory Network
National Laboratory Training Conference

Idaho Sentinel Laboratory Network
# IBL Resources – www.statelab.idaho.gov

## Idaho Bureau of Laboratories (IBL)

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<thead>
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<th>Programs</th>
<th>Announcements</th>
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</thead>
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<tr>
<td>Chemical Threat Testing</td>
<td>Laboratory Response Network for Chemical Threats (LRN-C); CDC guidance documents; submission forms</td>
</tr>
<tr>
<td>Clinical Lab Certification</td>
<td>CLIA regulations and registration forms</td>
</tr>
<tr>
<td>Clinical Testing</td>
<td>Microbiology, serology, and virology in clinical samples; submission forms</td>
</tr>
<tr>
<td>Drinking Water Lab Certification</td>
<td>Environmental labs for microbiological, inorganic, organic, and radiochemical analysis; drinking water certificates</td>
</tr>
<tr>
<td>Environmental Testing</td>
<td>Chemicals and bacteria in water and soil; contaminant fact sheets; submission forms</td>
</tr>
<tr>
<td>Food Testing</td>
<td>Bacteria and toxicsin in food matrices; submission forms</td>
</tr>
<tr>
<td>Sentinel Labs</td>
<td>Laboratory Response Network for Biological Threats (LRN-B); reference materials for Idaho's sentinel labs</td>
</tr>
<tr>
<td>X-Ray Licensure</td>
<td>X-ray and mammography regulations and licensure forms</td>
</tr>
</tbody>
</table>

## Bureau Guide

- **Sampling and Submission Guide**
  - Client Billing Form
  - **Fees Effective July 1, 2012**
    - IBL Supply Request
      - Online ordering
      - Print and fax order form
  - IBL Web Portal Access
    - Web portal
  - IBL Amended Information
    - Amended Information for Submitted Samples form
  - IBL Sample Receiving Location
  - Isolate and Specimen Request Application
    - **New!** Clinical Test Request Form
IBL Resources

• Clinical Forum issues
  ◦ quarterly

• In-Class Workshops
  ◦ Regional lab safety outreach
  ◦ Biological threat rule-out or refer
  ◦ Packaging and Shipping Division 6.2 Materials

• Virtual Trainings
  ◦ Webinars
  ◦ Online through APHL, CDC, or IBL
IBL Resources – Biorepository

• Collection of serum and bacterial specimens received from across the state

• Preserved, catalogued, and stored

• Agencies can request samples for test verification, proficiency testing, case comparison, whole genome sequencing, and antimicrobial research.

• [www.statelab.idaho.gov](http://www.statelab.idaho.gov) → “Isolate and Specimen Request Application” form
Ebola Supplemental Grants

By the Numbers

ELC awards
$90-240 Million to grantees annually**

5 state health departments + 8 members or U.S. affiliates + 6 of the largest local health departments = 6 grantees

Public Health Emergency Preparedness (PHEP) Cooperative Agreement Funding:

**Figures in millions

Source: CDC, FEMA, Division of State and Local Preparedness
Background

• Funding Sources:
  ◦ Spring 2015 – PHEP and ELC Ebola supplemental grants
  ◦ August 2016 – ELC grant: Project E, Enhanced Laboratory Biosafety and Biosecurity Capacity

• Purpose:
  ◦ To enhance lab safety capacity in public health laboratory jurisdictions
  ◦ To promote a culture of safety in the lab
Background

• IBL first focused in-house:
  ◦ Hired part-time Health & Safety Specialist and part-time Principal Microbiologist
  ◦ Purchased two QuantStudio qPCR instruments
  ◦ Purchased new autoclave and biosafety cabinet
  ◦ Purchased new PAPRs and stocked up on BSL-3 PPE
  ◦ Purchased Lectora software to create online training
  ◦ Became members of American Biological Safety Association International (ABSA)
  ◦ Attended training opportunities
Background

• IBL then shifted focus to Idaho sentinel labs:
  ◦ Purchased Category A shipping materials to distribute
  ◦ Purchased two PortaCount quantitative respirator fit testers
    ▪ Available upon request state-wide for agencies to use
  ◦ 2016 – Category A Packaging and Shipping Drill
  ◦ 2017 – Lab Safety Outreach Workshops and sentinel lab site visits
  ◦ Purchase safety awareness tools
    ▪ Wizard stick, Glo Germ kit, GHS-labelled bleach squirt bottle
Lab Safety Outreach Workshop

Description
Idaho Bureau of Laboratories (IBL) will conduct a one-day workshop that provides guidance and resources for hospital and clinical staff to work safely in the laboratory. Topics covered will include biological and chemical safety assessments, hazard identification and risk assessment, personal protective equipment (PPE), use of biosafety cabinets, and an overview of packaging and shipping infectious substances.

Target Audience
Hospital and clinical laboratories working with biological pathogens and hazardous chemicals.

Objectives
At the end of this program, participants will be able to:
- Discuss the partnerships between IBL and Idaho’s clinical laboratories.
- Implement appropriate safety practices within the clinical laboratory.
- Create and implement laboratory risk assessments.
- Demonstrate proper PPE donning and doffing.
- Describe the equipment for non-invasive packaging and shipping Division 6.2 infectious substances.

Faculty
- Michael Stewart, PhD, Deputy Lab Director, Alternative Pathogens Laboratory
- Wendy Loven, MHA, Business Analyst
- Mike Larsen, Division Administrator, Public Health Idaho North Central District
- Terri Fredrickson, MEd, Laboratory Manager, Public Health Idaho North Central District
- Anna Haggard, MEd, Laboratory Manager, Public Health Idaho North Central District

Other Information
Idaho Bureau of Laboratories is in compliance with continuing education programs in the clinical laboratory sciences by the XXXX P.L.C. Program. Individuals who successfully complete this program will be awarded 6.0 contact hours.

Level of Instruction: Intermediate

Tuesday, May 23, 2017
9:00 am - 4:00 pm
Hosted by and Location:
Public Health–Idaho North Central District
Large Conference Room
215 10th Street
Lewiston, Idaho 83501
208-799-1100

Registration:
Register at [https://www.eventbrite.com/e/131357274517](https://www.eventbrite.com/e/131357274517)
Please register by Thursday, May 18, 2017.

Agenda
8:00 Registration and Refreshments
9:30 Introduction
9:45 State Public Health Laboratory Overview
9:50 Safety in the Lab: Biocultural and Infectious Disease
- Handling the Open Container and Bacteriology Cabinet
- Laboratory Acquired Infections (LAI)
10:15 Break
10:45 Risk Management
12:00 Lunch
1:00 Bacteriology Glands
2:00 Personal Protective Equipment
2:30 Break
2:45 Packaging and Shipping Infectious Substances
3:30 Post-test and Certificate
4:00 Adjourn

Note: Lunch is provided as a working lunch.

Contact Richard Unruh with questions.
Phone: 208-344-1564
Email: richard.unruh@health.idaho.gov
Workshop Overview

• 9 a.m. – 4 p.m.
  ◦ Working lunch
  ◦ Guest lecturer – district epidemiologist

• Pre- and post-test

• Materials printed and provided in a blue binder, as well as on a USB flash drive

• Display table
  ◦ Lab signage examples, spill kits, PPE, packaging and shipping materials, Wizard stick
Workshop Curriculum

• Topics covered:
  ◦ State Public Health Lab Overview
  ◦ Safety in the Lab
  ◦ Risk Management
  ◦ Biosafety Cabinets
  ◦ Personal Protective Equipment
  ◦ Packaging and Shipping Infectious Substances
Workshop – Safety in the Lab

• Overview
  ◦ Definitions and guidelines
  ◦ Standard lab practices
  ◦ Primary and secondary barriers

• Biological Safety
  ◦ Disinfection vs. sterilization
  ◦ Biowaste disposal
  ◦ Biospill response

• Chemical Safety
  ◦ Hazard Communication Standard
  ◦ Proper chemical storage
  ◦ Chemical spill response
Workshop – Safety in the Lab

• Safety Communication
  ◦ Room signage
  ◦ Safety equipment
  ◦ Evacuation routes

• Training Requirements
  ◦ Bloodborne pathogens
  ◦ Exposure Control Plan
  ◦ Respiratory Protection

• Laboratory Acquired Infections
  ◦ Routes of infection
  ◦ Promote a culture of safety
Workshop – Risk Management

- Risk management components
  - Hazard identification (agent, host, procedure)
  - Risk assessment
    - different from IQCP risk assessment
  - Risk mitigation
  - Review cycle

- Risk assessment exercises
  - Risk assessment templates
  - Zika blood tube processing
  - Erythrocyte sedimentation rate

<table>
<thead>
<tr>
<th>Lab Safety Risk Management</th>
<th>VS.</th>
<th>Individualized Quality Control Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Framework for customizing a program to develop and promote biosafety and biosecurity in the lab.</td>
<td></td>
<td>Framework for customizing a quality control program for lab test systems to ensure accurate test results.</td>
</tr>
<tr>
<td>- Risk assessment</td>
<td></td>
<td>- Risk assessment identifies potential problems that may occur in the testing process, beginning with specimen collection (pre-analytic), through analysis (analytic), until the final test result is reported (post-analytic).</td>
</tr>
<tr>
<td>- Risk Mitigation</td>
<td></td>
<td>- Specimen</td>
</tr>
<tr>
<td>- Risk Mitigation</td>
<td></td>
<td>- Test system</td>
</tr>
<tr>
<td>- Risk Mitigation</td>
<td></td>
<td>- Reagents</td>
</tr>
<tr>
<td>- Risk Mitigation</td>
<td></td>
<td>- Environment</td>
</tr>
<tr>
<td>- Risk Mitigation</td>
<td></td>
<td>- Testing personnel</td>
</tr>
</tbody>
</table>
Workshop – Risk Management

• Clinical lab setting – identify hazard situations
  ◦ Chemistry
  ◦ Hematology
  ◦ Microbiology
  ◦ Urinalysis

• Resources
  ◦ APHL Clinical Laboratory Biosafety Risk Management Program Assessment Checklist
  ◦ BMBL
  ◦ APHL Biosafety and Biosecurity website
Workshop – Biosafety Cabinets

• Difference between a BSC and a chemical fume hood

• BSC class and type

• View Eagleson Institute BSC training video

• Certification and repairs

Do you use a BSC or CFH at your facility?
What Class and Type of BSC do you have?
When was your BSC last certified?
Workshop – PPE

• Define PPE
  ◦ Gloves
  ◦ Lab coat
  ◦ Eye protection
  ◦ Respirators

• Discuss PPE policies at facilities
  ◦ Mandatory versus voluntary
  ◦ Donning/doffing order

• Glo Germ exercises
  ◦ When doffing gloves
  ◦ When washing hands
Workshop – P&S Infectious Substances

• Disclaimer
  ◦ IBL guidance does not certify a person to package and ship Division 6.2 Infectious Substances.

• Highlights on:
  ◦ Regulatory agencies (DOT, IATA, USPS)
  ◦ Division 6.2 Infectious Substances
  ◦ Category A versus Category B and classification process
  ◦ Triple package versus Materials of Trade exception

• Tips and tricks from the 2016 P&S drill

• Resources
2016 Category A Packaging and Shipping Drill
Category A Drill Overview

- Facilitated by Cassie Dayan, Health & Safety Specialist
- Offered to Idaho sentinel labs
- Strictly voluntary
- Category A boxes and Category A sample (STEC culture) mailed to participants
- P&S refresher PowerPoint provided
- FedEx air mode of transportation
  - Typical cost $50 per Category A package
  - Overall FedEx costs for this drill was $1700.
Category A Drill Overview cont’d

• Coordinated week for participant to package and ship sample

• Shipped sample to evaluator (IBL)
  ◦ If lab was local to Boise, package was shipped to Montana state public health laboratory for evaluation.

• Package evaluated and results reported back to lab

• Emphasized: It is illegal to ship a Category A box without a suspected Category A sample inside, unless a special permit is provided.
# IBL Evaluation Form

**Idaho Bureau of Laboratories (IBL)**

Packaging & Shipping Evaluation Checklist for Category A Samples

<table>
<thead>
<tr>
<th>Submittal Lab/Contact Name/Phone Number:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Description/LIMS #:</td>
<td></td>
</tr>
<tr>
<td>Date: ____________________ IBL Evaluator: ____________________ Was IBL notified prior to shipping? Yes__ No__</td>
<td></td>
</tr>
</tbody>
</table>

**Shipping Method:** FedEx | Courier | Other | Compliant |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Declaration form is present.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Shipper name and address</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Consignee name and address</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Transport details: CARGO AIRCRAFT ONLY crossed off</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Shipment type: RADIOACTIVE crossed off</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o UN 2814, Infectious substance, affecting humans</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Technical name in parentheses: (Suspected Category A Infectious Substance)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Class or Division: 6.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Quantity and type of packaging: e.g. 3 mL, all packed in one fiberboard box</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Packing instructions: 620</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Form is signed, name and title</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Shipper’s Declaration for Dangerous Goods**

- • Declaration form is present.
- • Shipper name and address
- • Consignee name and address
- • Transport details: CARGO AIRCRAFT ONLY crossed off
- • Shipment type: RADIOACTIVE crossed off
  - o UN 2814, Infectious substance, affecting humans
  - o Technical name in parentheses: (Suspected Category A Infectious Substance)
  - o Class or Division: 6.2
  - o Quantity and type of packaging: e.g. 3 mL, all packed in one fiberboard box
  - o Packing instructions: 620
- • Form is signed, name and title
### IBL Evaluation Form cont’d

<table>
<thead>
<tr>
<th>OUTER PACKAGING AND LABELING</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Proper UN certified Category A shipper kit (e.g., Infekta, Saf-T-Pak)</td>
</tr>
<tr>
<td>- Shipper name and address</td>
</tr>
<tr>
<td>- Consignee name and address (Attention to appropriate IBL laboratory or staff)</td>
</tr>
<tr>
<td>- Name and phone number of Responsible Person</td>
</tr>
<tr>
<td>- Class 6 Infectious Substance label</td>
</tr>
<tr>
<td>- UN 2814 / Infectious Substance, Affecting Humans label with technical name underneath in parenthesis: (Suspected Category A Infectious Substance)</td>
</tr>
<tr>
<td>- Quantity of sample (e.g., 3 mL)</td>
</tr>
<tr>
<td>- All hazard labels placed properly on same side of box</td>
</tr>
<tr>
<td>- Airway bill included and marked properly</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INNER PACKAGING</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Styrofoam box within outer shipping box, or, if ambient, secondary container is present</td>
</tr>
<tr>
<td>- Secondary pressure container: cannot mix manufacturer packaging materials; if Infekta, use 95 kPa bag; if Saf-T-Pak, use Tyvek envelope with inner clear bag</td>
</tr>
<tr>
<td>- Itemized list of contents on secondary pressure container (e.g. “Infectious Substance Affecting Humans; UN 2814; 1 x 4 mL; 3 mL total”)</td>
</tr>
<tr>
<td>- Absorbent sheet around primary receptacle</td>
</tr>
<tr>
<td>- Primary receptacle: must be leak-proof</td>
</tr>
<tr>
<td>- NOTE: If a culture, send on slant (petri plate is against IATA regulations)</td>
</tr>
<tr>
<td>- Biohazard symbol on primary or secondary container</td>
</tr>
</tbody>
</table>

**Comments:**

---

v. 08/2016
Issues Encountered

• Supplying IBL with documentation that participants were certified to package and ship Division 6.2 Infectious Substances

• Not repackaging the STEC sample sent to them – shipped back to IBL in original inner packaging

• Labelling incorrectly the outside of shipping box
  ◦ Package was returned to participant – FedEx still charged
Issues Encountered cont’d

• Incorrectly filling out Shipper’s Declaration of Dangerous Goods form
  ◦ Written by hand
  ◦ Not in color
  ◦ Package was returned to participant – FedEx still charged

• Difficulty in setting up FedEx account to ship a Category A package

• Commitment!
  ◦ 22 labs planned to participate; 16 ultimately completed drill.
**Do This, NOT That:**

### Category A Packaging and Shipping

| **DO** follow IBL directions when participating in drills. |
| **DO** have quarterly internal shipment drills to help prepare certified shippers and reduce the likelihood of returned shipments. Contact IBL at 208-334-2235 for drill ideas. |
| **DO** always have at least one UN certified Division 6.2 Category A box available. |
| **DO** have access to a color printer for printing the DG forms, as they must be in color. |
| **DO** set up your FedEx account to allow shipment of a Category A package. Contact 800-GoFedEx and ask for the DG specialist in your area for assistance. |
| **DO NOT** handwrite the DG form. Only computer-generated or typed forms are acceptable, and there must be four copies of the DG form. |
| **DO NOT** use an incorrect DG form template. There are templates available online that have the wrong DG red slanted bars. For a correct template, consider using the Saf-T-Pak software: [https://www.saftpak.com/Support/Support.aspx](https://www.saftpak.com/Support/Support.aspx) |
| **DO NOT** mislabel the outside of the package:  
- The shipper or a designated person at the shipper’s facility is the responsible party.  
- The quantity of contents should be visible on the box.  
- **DO** use the current Infectious Substance label that was updated in 2014.  
- **DO NOT** handwrite on the UN2814 label. |
Next Steps
Next Steps

• Offer drill again (voluntary) in Fall 2017 – Spring 2018

• Consider using Category A special permit, if available.

• Give more explicit instructions and on-hand resources.

• Offer drill during a planned week or as unannounced.
Next Steps

• Supply participating labs with at least two Category A shipping materials.

• Determine if labs have at least two certified shippers.
  ◦ If not, encourage to take CDC online course.

• Encourage labs to conduct internal P&S drills.
  ◦ Don’t actually ship out the sample.

• Reach out to exclusive use couriers to ensure they have appropriate hazmat training.
Pat Payne giving “Packaging and Shipping Division 6.2 Materials” in Lewiston, ID, 6/22/17; sponsored by NLTN
Thank you!

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