Bio-Threat Agents: Environmental Sampling

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NIOSH

CDC
Classification

- Obligate parasites (must have a living host)
  - viruses
  - bacteria
  - rickettsia

- Facultative saprophytes (will utilize dead organic material)
  - fungi
  - bacteria
Size Ranges of Microorganisms

- Fungal Spore
- *Escherichia coli*
- Rabies Virus
- Polio Virus

1 µm
# Mechanisms for Microbial Dispersal

**Linear Distances**

<table>
<thead>
<tr>
<th>Very Short</th>
<th>Medium</th>
<th>Long</th>
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<tbody>
<tr>
<td>Motility</td>
<td>Sewage</td>
<td>Wind</td>
</tr>
<tr>
<td>Gliding Motion</td>
<td>Ground Water</td>
<td>Animal Vectors</td>
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<td>Eroding Soil</td>
<td>Water Currents</td>
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<td>Inanimate Objects</td>
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</table>

- **Inanimate Objects**
- **Ground Water**
- **Eroding Soil**
- **Sewage**
- **Wind**
- **Animal Vectors**
- **Water Currents**
- **Inanimate Objects**
Health Concerns

- Infections
- Immunologic Reactions
- Toxic Effects
Infectious Disease

- Pathogenicity
- Virulence
- Relationship between virulence (V), numbers of pathogens or dosage (D), and resistant state of the host (RS)

\[
\text{Infectious Disease} = \frac{V \cdot D}{RS}
\]

- Colonization
- Invasiveness
Infectious Disease Terminology

- Portal of entry
- Exposure vs. infection
- Clinical vs. subclinical or asymptomatic infection
- Carrier state
- Opportunistic infection
- Human pathogen vs. virulence
- Immunosuppression
Infectious Disease

Pathways

- Respiratory
- Oral (via ingestion)
- Contact
- Penetration
- Vectors (via insect bite)
Investigative Components

- Environmental Characterization
- Epidemiology
- Physician
- Sampling
Investigative Components

Environmental Characterization

- Opportunity to
  - Characterize the exposure environment
  - Search for the contaminant source
  - Establish a sampling plan (if needed)
Investigative Components

- Physician consultation
- Epidemiology
- Environmental Characterization
- Bioaerosol sampling
Environmental Sample Types

Bulk

Surface

Air
Sampling Bioaerosols

- Where to Sample?
Sampling Bioaerosols

- Where to Sample?
- Sampler Selection

- Mycotoxins
- Spores
- Fungi
- Protozoans
- Endotoxins
- Bacteria
Culturable Air Samples

Pros
- ID species
- consensus reference standard

Cons
- underestimate total concentration
- nutrient media is selective
- small sample window
- labor intensive
- complicated data interpretation
Non-culturable Air Samples

Pros
- easy to implement
- measures total load
- samples collected full-shift
- collection of PBZ

Cons
- nonspecific (viable and nonviable)
- results can be obscured by debris
  - For counts
  - NOT for PCR and immuno assays
- requires qualified analytical lab
Bioaerosol Samplers

**BACTERIA AND FUNGI**
- Andersen cascade impactors
- SAS
- Biotest
- Slit-to-agar
- All glass impinger
- SKC Biosampler
- Filter cassettes

**SPORES**
- Spore trap
- Filter cassette
- Zefon Air-Q Cell
Bioaerosol Samplers
Andersen Two-stage Cascade Impactor

Air Flow

Petri Dish
Bioaerosol Samplers

Slit-to-agar Sampler

Air Flow

Particle Impactor Inlet

Rotating Base

Petri Dish

Timer
Bioaerosol Samplers

Filter Cassette

Air Flow

Back-up Pad

Filter
Sampling Bioaerosols

- Where to Sample?
- Sampler Selection
- Sampling Techniques
Sampling Techniques

- Sampler Calibration
- Sampler Disinfection
- Sampling Time?
- Quality Control
- Nutrient Media
Sample Analysis

- Incubation of sample plates

22 - 56°C
Sample Analysis

- Incubation of sample plates
- Viable microorganism and fungal spore counts
Bioaerosol Concentration Calculation

\[ \text{Conc} = \frac{\text{Cnt}}{Q_s \cdot t} \]
Sample Analysis

- Incubation of sample plates
- Viable microorganism and fungal spore counts
- Enumeration of taxa
Clinical Environmental
IH Governing Principles

- Recognition
- Evaluation
- Control
Bacillus anthracis

- Bacterium
- Aerobic
- Non-motile
- Gram positive
- 1 to 5 µm endospores
- Respirable
- Resistant to environmental extremes
- Electrostatic (?)
NATURALLY OCCURRING ANTHRAX CASES

Key
- Epidemic: widespread in animals
- Endemic: regularly affects animals

SOURCE: WHO
Where It All Began...

- FL - October 3, 2001
Florida-AMI

Cases: 2 inhalation (1 death)
- 1 of >1000 nasal swabs +

Exposure Assessment:
- AMI worksite: widespread contamination
- Postal facilities: low to no contamination
- No opportunity to ID source
NJ - Hamilton P&DC

- Cases: 5 cutaneous; 2 inhalation
- None of > 1,200 nasal swabs +
- Exposure Assessment:
  - Hamilton: widespread contamination
  - Postal facilities: little to no contamination
NYC - Multiple sites

- Cases: 7 cutaneous
  - *NY Post, NBC, ABC, & CBS*
- None of > 2,500 nasal swabs +
- Exposure Assessment
  - Morgan P&DC
  - Residences
- Known letters to NY Post & NBC
Washington, D.C.

- Cases: 5 Inhalation
  - (2 deaths)
- 28 nasal swabs +
- Exposure Assessment
  - Brentwood P&DC: widespread contamination and mail facilities up and downstream
  - Capital Hill: contamination
    - Hart, Dirksen, Longworth, Supreme Court
  - Department of State annex: contamination
- Others
The “Letters”

- 1-2 grams of spores
- 1 gram = $1 \times 10^{12}$ spores
- 2 grams ≈ 200 million doses
Daschle Letter’s Path

Officials have tried to trace the path of the contaminated letter sent to Senate Majority Leader Thomas A. Daschle (D-S.D.):

1. Letter is postmarked Oct. 9 in Trenton, N.J.

2. Arrives at the Brentwood postal facility for sorting.

3. Transferred to the postal facility at Half and P streets SE.

4. Delivered to the Hart Senate Office Building and opened by an aide.

BY LARIS KARKLIS—THE WASHINGTON POST
Outliers

- 2 Inhalation cases
  - NY health care worker
  - CT elderly woman

- Exposure Assessment
  - Residence
  - Work environment (NY)
  - Subway (NY)
Overall Scenario

Aerosol Transport

Aerosol Measurement

Aerosol Inhalation

Aerosol Source Characteristics
Secondary Sources (Resuspension)
Aerosol Losses to Surfaces
Aerosol Size Range

Particle Diameter (µm)

Concentration (#/cm³ / D ln d)

- Viruses
- Bacteria
- Mycobacteria

Lab

Field

Mechanical Generation

- Viruses
- Bacteria
- Spores

CDC
Aerosol Particle Behavior

- Settling
- Impaction
- Charge effects
- Release from surfaces
- Agglomeration/ De-agglomeration
Particle Settling in Air

Time to settle 5 feet by unit density spheres

- 0.5 µm: 41 hours
- 1 µm: 12 hours
- 3 µm: 1.5 hours
- 10 µm: 8.2 minutes
- 100 µm: 0.5 seconds

Aerodynamic diameter: diameter of unit density sphere that settles at the same velocity as particle in question.
Particle Settling in a Closed Room

Stagnant air

Conc. vs. Time

Turbulent air

Conc. vs. Time
Particle Transport

- Most losses by settling
- Complex flow systems
- Turbulence production
- Doors, people, fans, ventilation

Ventilation system
No numeric criteria for interpreting environmental measurements
Preparation to Sampling

- Training
- Safety
- Record Keeping/Documentation
- Sampling Strategy
  - Define the goal
  - Consult with building engineer/HVAC
Purpose of Environmental Sampling

Must be hypothesis driven!

- Determine presence of *Bacillus anthracis* spores
- Determine extent and degree of contamination
- Support medical treatment and clean-up decisions
- Provide guidance on re-occupancy
Investigative Sampling Strategy

*Anthrax Outbreak*

- Follow the mail
- High traffic areas
- Ventilation system
- Areas that collect dust
Consider...

- Dissemination
  - Air
  - Fomites
- Surfaces
  - Porous versus non-porous
- Validated sampling protocols
- Methods of analysis
What Was Sampled?
Anthrax Outbreak Investigation

- Furniture (equipment)
- Floors
- Ventilation system
  - Filters
  - Return air grills
- Vehicles
- Clothing

Source: EPA photos during Capitol Hill Clean-up
Environmental Sampling Issues

- Collection efficiency
- Recovery efficiency
- Limit of detection
- Confirmatory testing
- Shipping
Environmental Sample Types

- Bulk
- Air
- Surface
Procedures for Collecting Surface Environmental Samples for Culturing *Bacillus anthracis*

Preface
The decision to collect environmental samples for culturing *Bacillus anthracis* should be made by medical, environmental, and industrial hygiene professionals familiar with the organism and with the environmental sampling methodologies described in this document. This decision should be based on the nature and location of the suspected contamination, the medical diagnoses and opinions, the potential for the contaminant to migrate, and the activity for which the facility is used, following a pre-planned sampling strategy. Representatives from local, state, and federal agencies should be consulted during the decision-making process.

Environmental sampling can be used to help determine the extent and degree of contamination, to support decisions regarding the need for cleanup, and to provide guidance regarding when cleanup is adequate to permit re-entry into an area. The use of experienced investigators to conduct the environmental sampling will provide the best probability of locating and identifying *B. anthracis* spores if present.

Currently, no environmental exposure standards exist for *B. anthracis* spores. Investigators who review and interpret the results of environmental sampling for such spores must consider these uncertainties and use professional judgment in interpreting any positive or negative findings.
Predominant Sampling

- Surface
  - Swabs
  - Wipes
- Vacuum
  - Filter “sock”
  - 37-mm filter cassette
- Bulk
Field Validation of Environmental Surface Samples

Dr. Wayne Sanderson, CDC/NIOSH
Objectives

- Compare levels of Ba in side-by-side surface wipe, swab, and vacuum samples to compare relative efficiencies in collecting spores.
- Compare results of culture analysis with PCR analysis for the presence of Ba spores in extracts of surface samples.
- Conduct additional surface sampling to more better characterize distribution of Ba spores throughout facility.
- Evaluate effectiveness of clean-up efforts to remove spores from contaminated surfaces.
Methods

- Dry swab, wet swab, wipe, and HEPA vacuum samples collected adjacent in areas suspected to be contaminated with Ba spores
- Samples collected in randomized fashion
- Wipe and swab samples processed on-site
- CDC laboratory in Atlanta
- On-site by PCR
- HEPA vacuum samples analyzed by a contract laboratory
- Results standardized to CFU/in²
Surface Sampling Study

Conclusions

- Good agreement between wipe and HEPA vacuum samples on non-porous surfaces
- Poor agreement between swabs and HEPA & wipe samples
  - Wet swabs did not detect > 33% of time
  - Dry swabs did not detect > 66% of time
- Dry swabs should not be used to sample for B. anthracis environmental contamination
Surface Sampling Study

Conclusions

- Wet swabs
  - Sample crevices, inside machinery, difficult locations
- Wipes
  - Light dust loading
- HEPA vacuum
  - Heavy dust loading
  - May cover larger surface area

*Complete study published in Emerg Infect Dis 2002 Oct 8 (10).*
Air Sampling

- Culturable
  - Cascade impactors
  - Impingers
  - Filtration

- Non-culturable (PCR or immuno assay)
  - Impingers
  - Filtration
Air Samples Collected for Anthrax

Initial Response

- Hart Building
  - 37-mm filter cassettes
  - Andersen cascade impactors

- AMI Building
  - Andersen cascade impactors
  - Slit-to-agar cascade impactors
Air Samples Collected for Anthrax Remediation

- Daschle Suite
- Mail Facilities
  - USPS PD&C
  - State Department and WH mail annex
- AMI Building

- Cascade impactors
  - Andersens, SAS
- 37-mm filter cassettes
- DFU
Field Validation of Environmental Air Samples

Robert McCleery, CDC/NIOSH
Evaluation Methods

- Wipe sampling
- Air sampling
  - Andersen single-stage cascade impactor using tryptic soy agar (TSA) with 5% sheep blood
  - Filter cassette sampling
    - Mixed-cellulose ester (MCE) filters, 37-mm, 0.8 µm pore size, 2 Lpm
    - Polytetrafluoroethylene (PTFE) filters
    - Gelatin filters, 37-mm, 3 µm, 2 Lpm
    - Dry filter unit (DFU) with polyester felt filter, 1/8 inch, 3 µm, ~400 Lpm
Wipe Sampling

- Composite samples used sterile polyester/rayon pads moistened with sterile water.
- Five samples collected around jogger, feeder, and reader.
- Composite samples collected of all bins in a column.
Air Sampling

- Prior and subsequent to DBCS operation
- Containment built around machine
  - Volume = 1785 cu. ft. (70’ x 15’ x 7’)
- Six sample locations around machine
- A “test deck” was run through the machine during the 45 minute operation time
  - 6,521 “test deck” sheets run through
Sample Locations

Sample locations 1 through 6 contained MCE, PTFE, and GEL filters, while Andersen samples were located at 1-5.
Air Sampling

- 13 Andersen samples at each location
  - 10 collected in succession every ten minutes over an approximate 2-hour period in each location
  - 1 sample collected every 2-hour session over a 6-hour period

- Filter cassettes
  - 2 MCE and PTFE samples each location
    - 1 2-hour session and 1 8-hour session
  - 6 GEL samples each location
    - 2 1-hour samples per 2-hour session and 4 2-hour samples per 8-hour session

- DFU
  - 1 2-hour, 1 2-hour modified, and 1 8-hour
<table>
<thead>
<tr>
<th>Sample Media</th>
<th>Time Period</th>
<th>Prior to DBCS Operation (10% of pellet)</th>
<th>Prior to DBCS Operation (remaining pellet)</th>
<th>Subsequent to DBCS Operation (10% of pellet)</th>
<th>Subsequent to DBCS Operation (remaining pellet)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MCE</td>
<td>120 min</td>
<td>0% (0 of 6)</td>
<td>17% (1 of 6)</td>
<td>50% (3 of 6)</td>
<td>100% (3 of 3)</td>
</tr>
<tr>
<td></td>
<td>480 min</td>
<td>0% (0 of 6)</td>
<td>0% (0 of 6)</td>
<td>17% (1 of 6)</td>
<td>100% (5 of 5)</td>
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<tr>
<td>PTFE</td>
<td>120 min</td>
<td>0% (0 of 6)</td>
<td>0% (0 of 6)</td>
<td>50% (3 of 6)</td>
<td>100% (3 of 3)</td>
</tr>
<tr>
<td></td>
<td>480 min</td>
<td>0% (0 of 6)</td>
<td>17% (1 of 6)</td>
<td>50% (3 of 6)</td>
<td>100% (3 of 3)</td>
</tr>
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<td>Gel</td>
<td>120 min</td>
<td>0% (0 of 12)</td>
<td>8% (1 of 12)</td>
<td>50% (6 of 12)</td>
<td>100% (6 of 6)</td>
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<td>0% (0 of 24)</td>
<td>29% (7 of 24)</td>
<td>47% (8 of 17)</td>
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<td>DFU</td>
<td>120 min</td>
<td>0% (0 of 2)</td>
<td>100% (2 of 2)</td>
<td>100% (2 of 2)</td>
<td>*</td>
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<tr>
<td></td>
<td>480 min</td>
<td>0% (0 of 1)</td>
<td>100% (1 of 1)</td>
<td>100% (1 of 1)</td>
<td>*</td>
</tr>
<tr>
<td>And</td>
<td>120 min</td>
<td>16% (8 of 50)</td>
<td>n/a</td>
<td>98% (49 of 50)</td>
<td>n/a</td>
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<tr>
<td></td>
<td>360 min</td>
<td>27% (4 of 15)</td>
<td>n/a</td>
<td>67% (10 of 15)</td>
<td>n/a</td>
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</table>
Discussion

Prior to machine operation...

- Wipe samples collected at ~ Bin 100 to the end of machine indicated confluent growth.
- Wipe samples indicate that DBCS machine was still highly contaminated with *B. anthracis* spores.
- Positive Andersen samples did not seem to be in any particular order or indicate some event during the 8-hour sampling period that would have generated spores to be collected.
Discussion

During & subsequent to machine operation...

- Wipe samples collected ~ Bin 100 to the end of the machine indicated confluent growth.
- Andersen initial analysis indicates declining number of colonies per sample as time passed during 8-hour session.
  - One sample was negative during the first two hours of sampling.
  - Indicates DBCS machine aerosolized a large amount of spores when in operation.
Discussion con…

During & subsequent to machine operation...

- Approximately ¼ to ½ of the MCE, PTFE, and GEL samples were positive.
- MCE and PTFE positive samples did not seem to be consistently located at any one particular sampling location or time.
- GEL filters seemed to be more consistently positive at Stations 3 and 4.
- Positive GEL samples were collected in the first four hours of the 8-hour sampling period.
- DFU filters were positive.
- For the 2-hour sampling period, the total air volume sampled ~¼ of the enclosure air volume.
Conclusion

- All air sampling media capable of collecting B. anthracis spores
- Andersen more consistent when concentrations vary
- Andersen more sensitive
  - Positive air samples collected before machine was operated
  - Able to detect the subtleties of the decay curve
- Positive Andersen samples before the machine was operated suggest that even walking and light work in the enclosure may be sufficient to re-aerosolize anthrax spores
Conclusions cont...

- Other positive factors for using the Andersen sampler
  - Lower risk processing for the laboratory
  - Quicker turn-around time
  - Less laboratory bias resulting from reduced amount of sample processing
Investigator PPE

- “Level C”
  - F-F PAPR w/ HEPA filters
  - Coated Tyvek® suit (w/hood)
  - Disposable rubber boots
  - Double gloves (nitrile, vinyl)
- Higher levels of protection may be required
Investigator PPE

Protecting Investigators Performing Environmental Sampling for *Bacillus anthracis*: Personal Protective Equipment

Workers conducting environmental sampling that places them at risk for exposure to *Bacillus anthracis*, the organism causing anthrax, should wear protective personal equipment (PPE), including respiratory devices, protective clothing, and gloves. The items described below are similar to those used by emergency personnel responding to incidents involving letters or packages. Emergency responders need to use greater levels of protection in responding to incidents involving unknown conditions or those involving aerosol-generating devices.

**Powered Air-Purifying Respirator with Full Facepiece and High-Efficiency Particulate Air (HEPA) Filters**

- The constant flow of clean air into the facepieces is an important feature of this respirator because contaminated air cannot enter gaps in the face-to-facepiece seal. These respirators also give wearers needed mobility and field of vision.
- Respirators should be used in accordance with a respiratory-protection program that complies with the OSHA respiratory-protection standard (29 CFR 1910.134).
- Respiratory facepieces for investigators should be assigned on the basis of results of quantitative fit testing.
- Wearing a properly functioning and powered air-purifying respirator with a full facepiece that is assigned to the wearer on the basis of quantitative fit testing will reduce inhalation exposures by 98% of what they would be without wearing this type of respirator.

http://www.bt.cdc.gov/DocumentsApp/Anthrax/Protective/Protective.asp
First Responder PPE

Interim Recommendations for the Selection and Use of Protective Clothing and Respirators Against Biological Agents

The approach to any potentially hazardous atmosphere, including biological hazards, must be made with a plan that includes an assessment of hazard and exposure potential, respiratory protection needs, entry conditions, exit routes, and decontamination strategies. Any plan involving a biological hazard should be based on relevant infectious disease or biological safety recommendations by the Centers for Disease Control and Prevention (CDC) and other expert bodies including emergency first responders, law enforcement, and public health officials. The need for decontamination and for treatment of all first responders with antibiotics or other medications should be decided in consultation with local public health authorities.

This INTERIM STATEMENT is based on current understanding of the potential threats and existing recommendations issued for biological aerosols. CDC makes this judgment because:

1. Biological weapons may expose people to bacteria, viruses, or toxins as fine airborne particles. Biological agents are infectious through one or more of the following mechanisms of exposure, depending upon the particular type of agent: inhalation, with infection through respiratory mucosa or lung tissues; ingestion; contact with the mucous membranes of the eyes, or nasal tissues, or penetration of the skin through open cuts (even very small cuts and abrasions of which employees might be unaware). Organic airborne particles
Laboratory Response Network for Bioterrorism
A Snapshot of the LRN

- Operational since Sept 1999
- Now 120 Confirmatory Reference labs providing identification of biological threat agents
- Includes state and local public health, federal, military, international, veterinary, food and environmental testing facilities, as well as chemical laboratories
- A variety of partners that span the spectrum of BT preparedness and response
Partnerships

Founding Partners

- CDC
- Association of Public Health Laboratories
- The Federal Bureau of Investigation
- The Department of Energy
Extended LRN Partners in Biological Terrorism Preparedness and Response

- American Association of Veterinary Laboratory Diagnosticians
- American Society for Microbiology
- Environmental Protection Agency
- Department of Agriculture
- Department of Defense
- Food and Drug Administration
- Department of Homeland Security
- Canada, UK, Australia
LRN Operational Suppositions

- System must be flexible in order to respond to both overt and covert events as well as integrate with law enforcement
- Frontline response begins at the local level
- Leverage existing Public Health infrastructure and the strength of collaborative partnerships
- Infrastructure investments should have dual use
- Laboratory-based biodetection must be rapid to support timely public health decision making
- Testing algorithms and reagents must be standardized for interoperability and consequence management
The LRN will be the strategic partnership framework for a coordinated system that integrates the operational strength of laboratory analytical capacity domestically and in conjunction with key global partners for preparedness and response to biological and chemical terrorism as well other urgent threats to public health and national security.
Front Line Response Begins at the Local Level
Time to Results

- **Viral Culture**
- **Bacterial Culture**
- **Real-time PCR**
- **TRF Immunoassay**
- **DFA**
LRN Mission

The LRN and its partners will develop and maintain an integrated national and international network of laboratories that can respond quickly to acts of biological or chemical terrorism and other public health emergencies.

Our Mission in Action

Bioterrorism Preparedness
- Anthrax attacks of 2001
- BioWatch

Public Health Emergency Response
- Severe Acute Respiratory Syndrome
- Monkeypox
National Laboratories

National laboratories currently include those highly specialized facilities operated by the CDC and the US Army Medical Research Institute of Infectious Diseases (USAMRIID). These facilities are responsible for maintaining BSL-4 containment and uniquely trained and vaccinated staff. Capacity for performing bioterrorism, handling highly infectious biological agents and detecting chimeras and recombinant engineering of organisms.
Reference Labs

Reference laboratories responsible for detection and confirmatory identification of biological threat agents in referred specimens and samples using rapid advanced technology and specialized assays, reagents and support services provided by the LRN. Made up of over 100 state and local public health, federal, military, veterinary, agriculture, environmental and food testing laboratories.
Sentinel Laboratories

Sentinel laboratories provide routine rule-out and referral functions using conventional methods and commercially available and approved diagnostic tests. Although these laboratories may not be equipped to perform the same tests as LRN Reference laboratories, they can test clinical specimens and low-risk environmental samples to determine if they should be shipped to confirmatory reference or national level laboratories for further testing.
Laboratory Testing Required in Support of Response Involved Both Clinical Specimens and Non-Clinical Samples

- Environmental samples for risk assessment
- Nasal swabs for epidemiological investigations
- Clinical specimens for detecting exposure and infection
- Culture isolates referred for confirmation
LRN Environmental Testing Load

- Sum of All ENV Samples Received
- Sum of ENV Samples from CT, NY, NJ, FL, DC, MD, VA, & PA
Proof of Concept

LRN Response to Oct-Dec 2001 Anthrax Events:

- DoD inclusive (25%)
  - 30,200 environmental workups performed

- CDC inclusive (6%)
  - 7,500 environmental workups

- PHL inclusive (69%)
  - 84,010 environmental workups

Total:

>121,710 environmental workups
Role of LRN in BioWatch

- LRN expedited, in collaboration with Homeland Security, the assay development, personnel training and lab supply for high throughput real-time PCR testing in LRN/BioWatch lab facilities.
- Testing is sustained on a daily basis in support of environmental monitoring to detect an aerosol release.
- Designated labs support air sampling operations in cities as well as special event needs.
- Testing algorithm uses screening and verification panels for target nucleic acid sequences of priority biothreat agents.
Role of LRN in BioWatch

- CDC (BPRP) staffed BioWatch labs with emergency federal hires.
- LRN working to facilitate integration of laboratory “confirmed PCR positive” result with subsequent response cascade in Public Health Response Plan for consequence management.
- LRN at CDC requested to facilitate performance review and determination of interoperability of assays used in DoD programs.
Smallpox

April 10, 2003 - LRN PCR to detect Variola major nucleic acid in clinical specimens provided to network.
May 30, 2003 - LRN-PCR to Detect SARS Coronavirus RNA in Respiratory Specimens provided to network.
Extrapolation...

- SARS
- BioWatch
- Ricin
Transport of Specimens
Biological Agents

- Infectious agents of humans, animals, and plants
- Toxins produced by microbes
- Genetic material
  - Potentially hazardous by itself
  - Potentially hazardous when introduced into a suitable vector
- Purified/concentrated or in “other” materials
Transportation/Transfer

Transportation
- Air, land, or sea
- Generally commercial conveyance

Transfer
- Exchanging materials between facilities
Protection from Exposure

- Rigorous packaging
  - Sturdy
  - Prevents leakage
- Appropriate labeling
- Documentation of hazardous contents
- Training of workers
Regulations

- Interstate transportation of biologic agents
  - Public Health Service: 42 CFR Part 72
- Hazardous materials regulations
  - Department of Transportation: 49 CFR Parts 171-178
- Ability to mail etiologic agents
  - United States Postal Service: 39 CFR Part 111; Codified in the Domestic Mail Manual 124.38; Etiologic Agent Preparations
- Occupational exposure to blood borne pathogens
- Dangerous goods regulations
  - International Air Transport Association (IATA)
General Packaging Requirements

- Triple packaging
  - Primary receptacle
  - Water tight secondary packaging
  - Durable outer packaging
- Certified to meet rigorous performance tests of DOT, USPS, PHS, and IATA
packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.
General Packaging Requirements

Labels

- To: and From:
  - Shippers phone number displayed
- Infectious substance label
  - Includes class or division
- Proper Shipping Name
  - Ex: Infectious substance affecting humans (Bacillus species), UN2814
- Cargo aircraft label (when appropriate)
General Packaging Requirements

Documentation

- Manifest
  - Identifies the contents
  - Place outside water tight container
- Chain of custody