DHS S&T’s Major Customers

Seven operational components receiving **over 85%** of DHS FY07 appropriated funds
An Overview of the Chemical and Biological Division

Nels Olson Ph.D.

Program Manager for Next Generation Biological Detection in the R&D Branch

Chemical and Biological Division
Science and Technology Directorate
Department of Homeland Security
Chemical & Biological Division Organization

Chemical & Biological Division (CBD)

- Division Head
- Deputy Division Head

Chief Technology Advisor

Chief Medical and Science Advisor

Chief Agriculture Advisor

Threat Characterization and Attribution Branch

Chemical and Biological R&D Branch

Agricultural Defense Branch

Transition Branch
Where Do Our Requirements Come From?

Directly from a Capstone Integrated Product Team (IPT)

- Co-chaired by DHS Office of Health Affairs (OHA) and DHS Infrastructure Protection (IP)
- Membership from other DHS operational arms
- Identified 50+ Capability Gaps in first IPT process (FY07)

And they in-turn, base their requirements on

- Homeland Security Presidential Directives (10, 7, 9, 18, 22)
- Congressional legislation & guidance
- National planning & implementation guidance – NIPP, FRP, NIMS, and the National Planning Scenarios
- Risk, vulnerability and mitigation studies
- Private, local, state inputs
DHS Plays an Integral Role in Implementing the National Biodefense Strategy

“Biodefense for the 21st Century”

THREAT AWARENESS
- Intelligence
- Assessments
- Anticipate future threats

PREVENT & PROTECT
- Diplomacy
- Interdiction
- Critical infrastructure protection

SURVEILLANCE & DETECTION
- Attack Warning
- Attribution

RESPOND & RECOVER
- Resp. Planning
- Risk Comm.
- Medical countermeasures
- Mass casualty care
- Decontamination

The Four Pillars of the National Biodefense Program
Detection Paradigms and Timeline

**THREAT**
- Attack is Planned
- Biological Threat Material is in Place

**RESPONSE**
- Detect to Protect
  - Detect the Attack Prior to Contamination of Infrastructure

**ATTACK OCCURS**
- Biological Threat Material Reaches Infrastructure and Population

**Detect to Warn**
- Move People Out of Harm’s Way to Provide Timely Response and Protection Measures

**Detect to Treat**
- Supply the Appropriate First Aid and Treatment

**SYSTEMS**
- IbADS
  - Instantaneous Biological Agent Detection System
- RABIS
  - Rapid Automated Biological Identification System
- LBADS
  - Low-Cost Bio-Aerosol Detection Systems
Early Detection & Treatment Play a Critical Role in the Biodefense Strategy
Rapid Bio-Detection Triggers & Confirmers

Goals
- Trigger sensors providing an alert of an elevation of biological aerosol particles within 2 minutes
- Triggered confirmer sensors to provide species-level identification of threat material within 10 minutes
- Continuously operating confirmer sensors to provide species-level identification of threat material every 2 minutes

Roadmap
- **FY08**: initiate extended field testing of trigger sensors
- **FY08**: BSL-2 level testing of confirmer sensors
- **FY09**: BSL-3 level testing of confirmer sensors
- **FY09**: initiate extended field testing of confirmer sensors
- **FY09**: pilot testing of trigger and confirmer sensor networks
Next Generation Biological Detection

- Design bioinformatics for nucleic acid signatures and toxin proteins and peptides
- Sampling
- Sample preparation
- Assays
- Instruments
- Data analysis
- Bioinformatic analysis for matching and probability determination
- Decision tools and network agnostic data integration
Scheme for Bio Detection and Analysis

- **Sample Collection**
  - Collected Sample Matrix
  - Sample Culling
  - Sample Matrix Whole Organisms
  - Gene Immuno Assays
  - Genetic Genomic Analysis

- **Intact Organisms**
  - DNA Sample Preparation
  - RNA Sample Preparation
  - Protein

- **Bucket of Extra Cellular Material**
  - Analyte Sample Preparation For Exogenous Toxins
  - Toxin Immuno Assays
Proper Sample Matrix Knowledge Increases Operational Lifetime, Adding Robustness

Accounting for and correcting contaminating DNA Matrix Effects in the Sample Preparation and Assay Steps gives lower CVs and more reproducible results.

Sacrificial surface introduced during week eight.
Sample Matrix Contamination Mitigation
A Cleaning Study via Total Organic Carbon
Case 1: 100% Designed, Synthesized and Pure Component Hybridization Analysis

(890,055 probe beads x 369,886 dye-labeled, perfect match, targets)
Presence of Signals in Complex Background of True Negatives

These are the low number density true positive signals

PMT Noise Level
Incorrect Normalization, Based on Assumptions about Background Distributions of True Negatives

<table>
<thead>
<tr>
<th>Methods</th>
<th>RAW + Quantile</th>
<th>RMA + Quantile</th>
<th>MBCB + Quantile</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAM</td>
<td>3648</td>
<td>4384 (20%)</td>
<td>4521 (24%)</td>
</tr>
<tr>
<td></td>
<td>No background correction just normalized using quantile method</td>
<td>Robust Multi-array Analysis (RMA) Ignores Miss Match probes when correcting the background</td>
<td>Takes into account Miss Match control probes</td>
</tr>
</tbody>
</table>

Median Normalized and MBCB used  
Quantile Normalized and MBCB used
Bioinformatic Design and Copy Number Variants, Strongly Effect Success of Analysis
Poor Design and Incidence of High Repeat

Design Scores

Repeat Component of Design Score

Lead to Poor Signal Intensities and Overall Failed Analyses

Continuous Variable Signal Intensity
Good Design with Low Copy Numbers

Design Scores

Repeat Component of Design Score

Lead to Acceptable Signal Intensities and Appropriate Analyses

Continuous Variable Signal Intensity
FY09 New Starts in Surveillance & Detection R&D

Portable Biological Agent Detector
• Provide capability to test samples for biological threat agents at site of collection
• Reduce possibility of biological agents escaping detection at ports of entry
• Decrease time to resolve “suspicious white powder” events

Viable Bioparticle Capture
• Augments BioWatch information by characterizing the viability of a threat during an attack
• More definitive post-event characterization of bioterrorist events
R&D to Develop Validated, Ultra-High Specificity Bio-Detection Assays

**Goals**

- Validated assays for Gen 2 & 3 BioWatch
- Operational capability to make high-confidence assays available for private sector and industry use
- Next generation assays for detecting enhanced and advanced threats

**Roadmap**

**FY08**: top 20 assays for Gen 2 BioWatch
**FY08**: initial set of Gen 3 assays
**FY08**: pilot the process for developing assays for private sector and industry use
**FY09**: initial operational capability for developing assays for private sector and industry use
Organized into three “Enhanced Homeland Security Capabilities” (EHC)

- **Chemical Analysis** (threat awareness and attribution) – provides fundamental knowledge that shapes problem understanding
- **Detection** – develops and demonstrates solutions to promote situational awareness
- **Response and Recovery** – develop solutions to enhance return to normal state

Addresses broad spectrum of chemical threats (chemical warfare agents, toxic industrial chemicals, non-traditional agents)

Coordinated with and leverages DoD and EPA efforts
Successful Transition of Major Programs to Our Customers

Gen 1, 2 BioWatch

Rapidly Deployable Chem Detection System (RDCDS)

BioWarning & IncidentQ Characterization System (BWIC)

Mobile Chemical Lab (PHILIS) to EPA
Challenges

Rapid detection of the unknown threat

- Engineered
- Emerging
- Advanced threat

Rapid interrogation of containers, suitcases, etc. for chem/bio

Microbial Forensics

- Fingerprint libraries vs. novel methods for rapid strain identification

Wide Area Restoration

- Rapid characterization of large areas
- Actionable information from microbial risk assessments
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