An Overview of the Chemical and Biological Division

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Department of Homeland Security

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Agenda

- DHS S&T Organizational Structure
- Requirements Development Process
- Biological & Chemical R&D Program
- Summary

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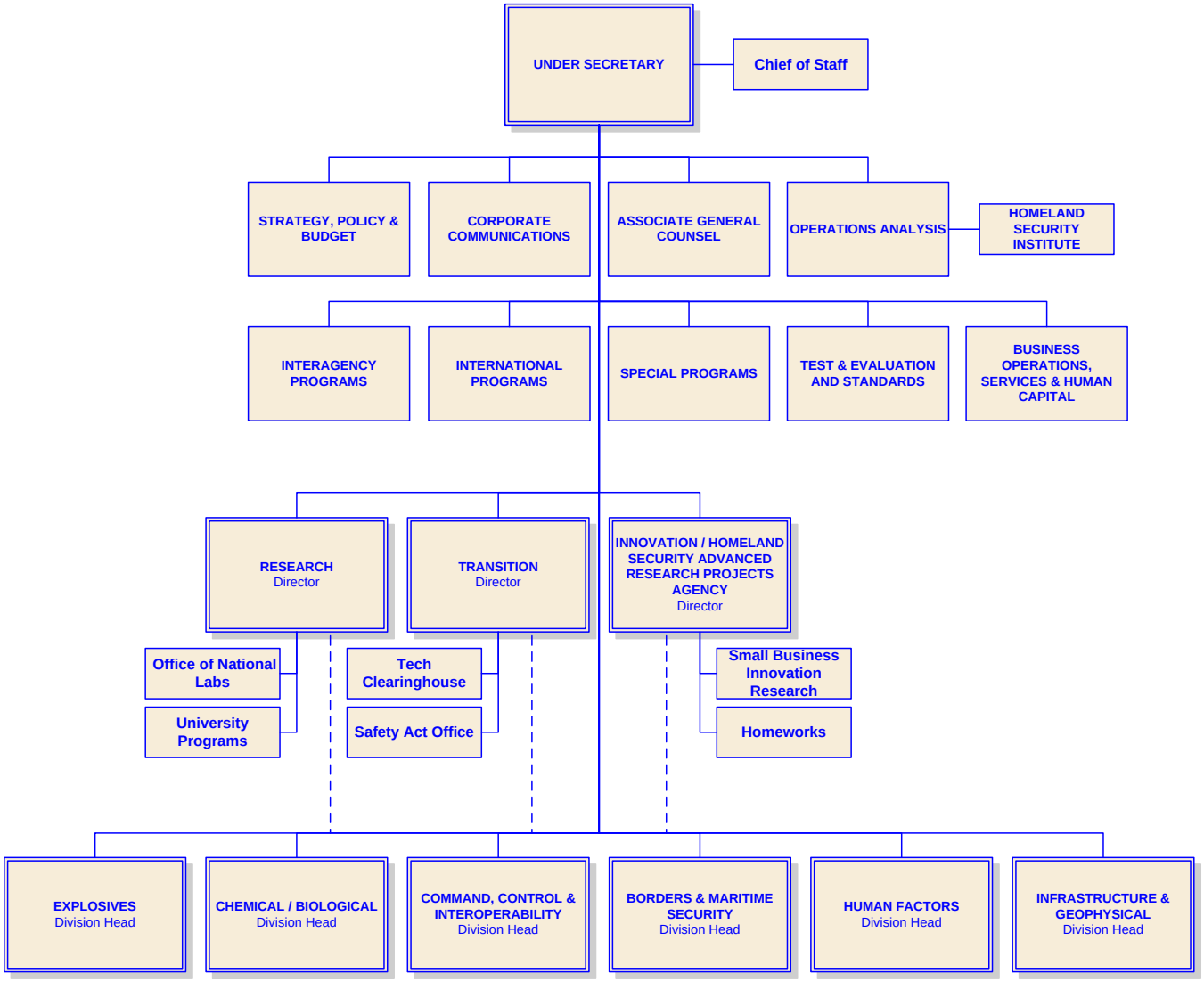
DHS S&T Organization



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DHS S&T Research and Development Strategy

Basic Research	Applied Research	Advanced Technology
Director of Research	**Director of Innovation/ HSARPA**	**Director of Transition**

Exploration of Fundamental Concepts (Enablers)

Demonstration & Delivery (Outputs)

DHS Unique/Essential

- Address primary DHS interest areas inS&T
- Opportunity-based investment
- High impacts/surprises
- Develop/maintain core Homeland Security S&T competencies

Support to Acquisition (EHCs)

- Program of Record Improvements
- Heavily requirements-based
- Generally evolutionary – Deliverable product to customer

Leap-ahead First Responder Capability

- Concept & need driven
- Transformational
- DHS Leadership priorities

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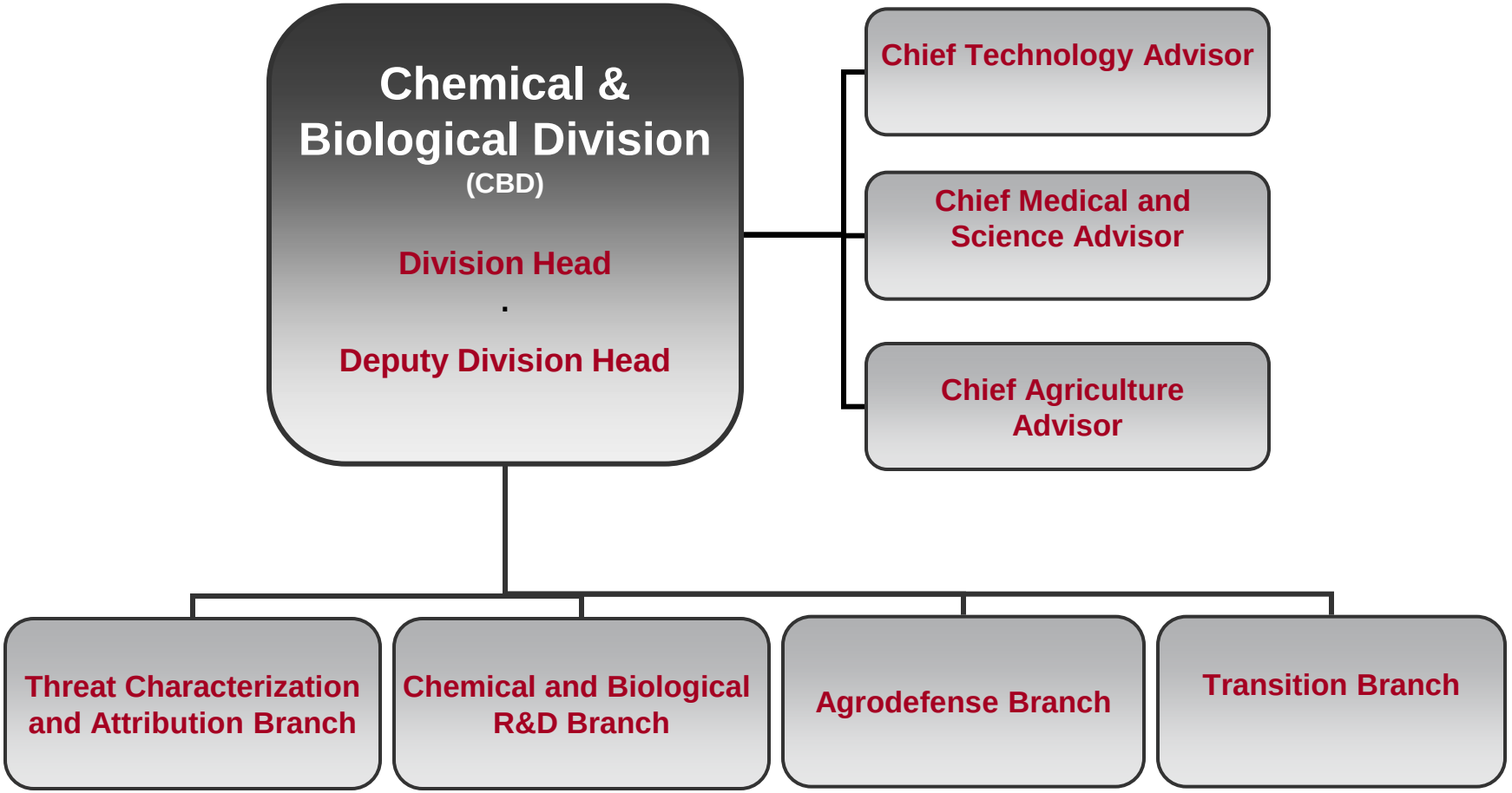
Chemical & Biological Division Organization



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Chemical and Biological Division Overview

Mission: to increase the Nation's preparedness against chemical and biological threats through improved **threat awareness, advanced surveillance and detection, and protective countermeasures**.

Key 5 year deliverables:

- Integrated CBRN risk assessments
- Anticipation of future & unconventional threats
- Chemical infrastructure risk assessment
- Fully automated Gen 3 BioWatch
- Integrated CBRN facility protection
- Restoration guidance & decision support tools
- National lead for operational biological and chemical forensics
- Decision tools and veterinary countermeasures for Foreign Animal Diseases (FADs)

IPT Co-Chairs: OHA, IP
DHS Drivers: OHA, IP, I&A, CBP, NPPD, PLCY, DNDO, Interagency Gaps
End-Users: HSC, HHS, FBI, USDA, IC, EPA, local public health, critical facilities

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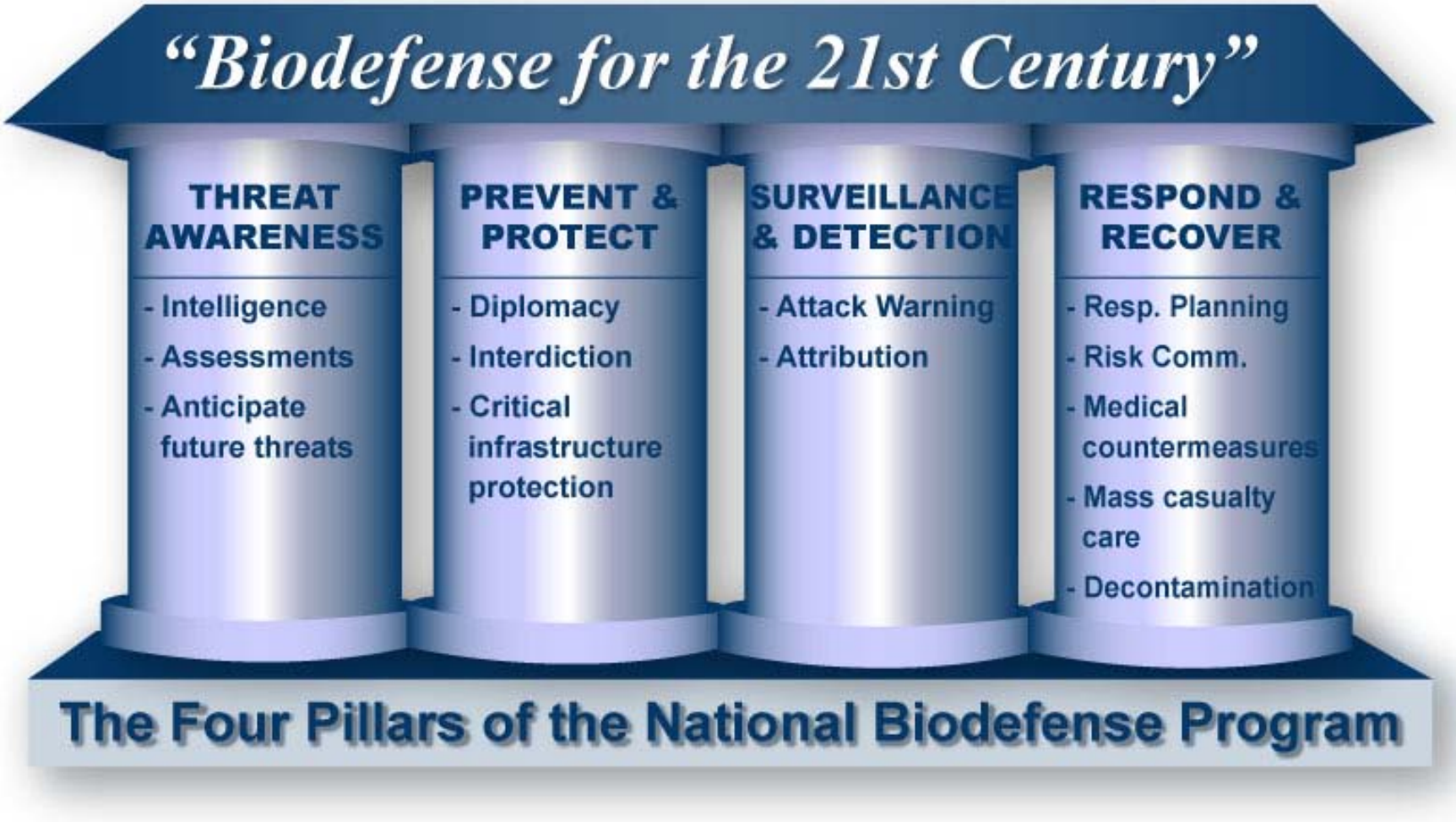
DHS Plays an Integral Role in Implementing the National Biodefense Strategy



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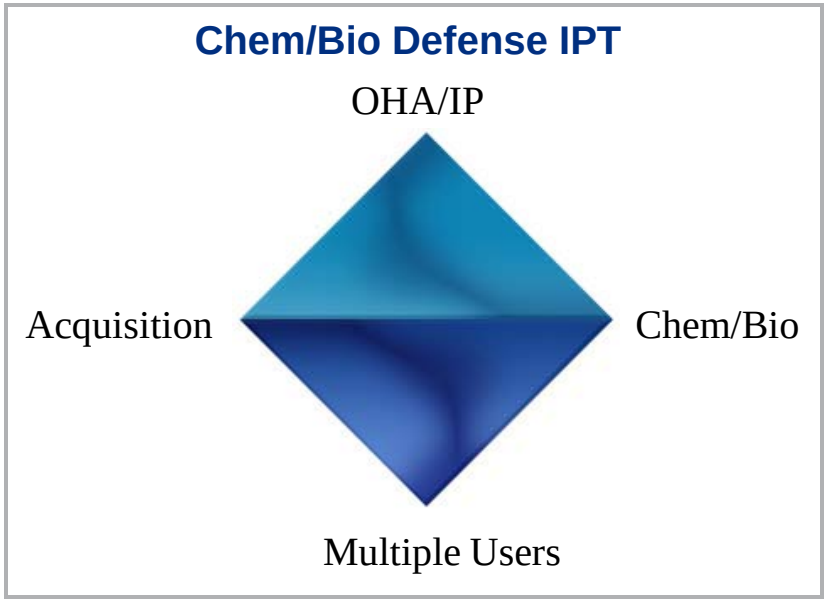
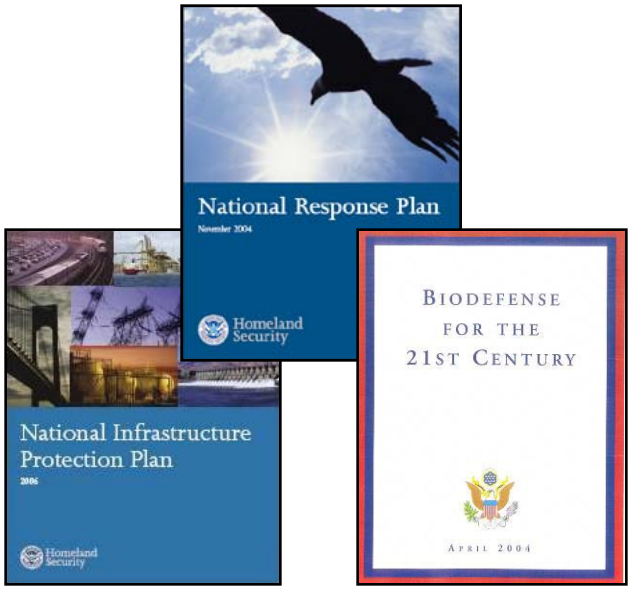
Where Do Our Requirements Come From?

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

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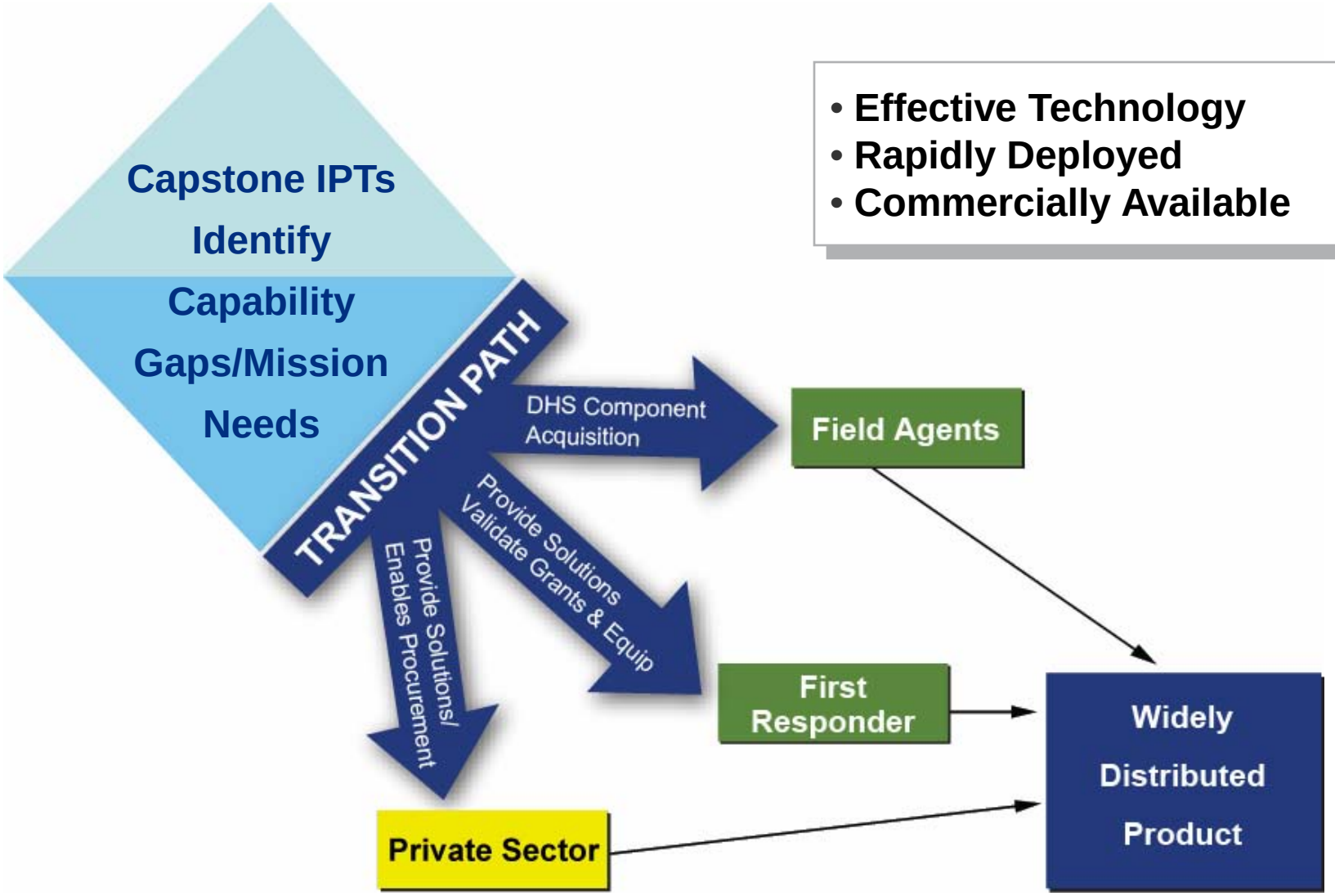
Transition Approaches



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DHS S&T's Major Customers

U.S. Citizenship and Immigration Services

Transportation Security Administration

FEMA

U.S. Immigration and Customs Enforcement

U.S. Customs and Border Protection

Seven operational components receiving *over 85%* of DHS FY07 appropriated funds

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In summary

- S&T Chem-Bio efforts are part of a national strategy as reflected through the requirements of the DHS operational offices

- We have already made a difference with first generation systems, e.g.

- Risk assessments, net assessments, and guidance help prioritize national investments and strategies
- Developed and transitioned to operation bio and chem detection systems (BioWatch, BWIC, PROTECT, RDCDS, PHILIS)
- Operational forensic capabilities
- Improved protocols and tools for protecting transportation facilities

- We are currently developing the next generation tools & systems to meet DHS and National requirements

- External program assessments review programmatic and/or technical relevance and focus course correction

- OPM Program Assessment Rating Tool (PART) score is EFFECTIVE (highest)
- Annual independent programmatic & strategic review is favorable

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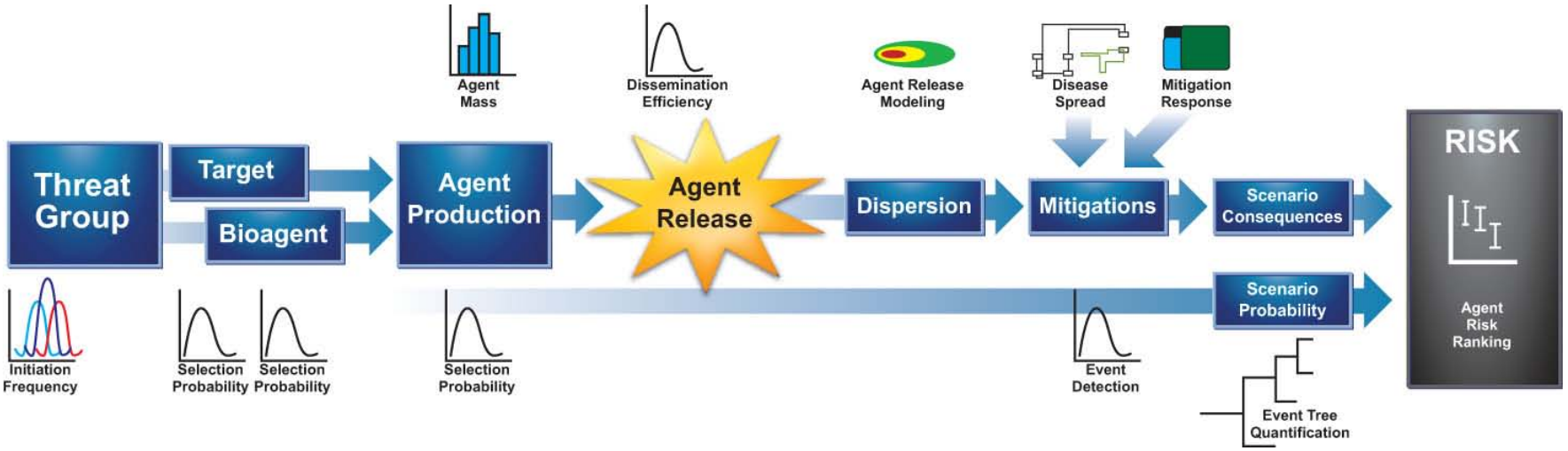
Risk Assessments to Guide National Biodefense Investments



Goals:

- Risk assessment capability to inform National priorities
- Prioritize risks for various sorting parameters (e.g., by level of casualty or class of scenarios)
- Identify key vulnerabilities and knowledge gaps

Roadmap

FY06: First BTRA 'vetted' and delivered to HSC; used to guide BioShield Material Threat Determinations

FY08: BTRA extended to engineered and agricultural threats with the addition of economic consequences

FY08: integrated CBRN RA completed

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Risk Assessments, Population Threat Assessments, and HHS Medical Consequence Modeling ➔ Material Threat Determination

BTRA/CTRA (risk of agent associated is related to each other)

- Intel
- Production capacity
- Dissemination efficiency
- Source Strength
- Exposure estimates
- Medical Countermeasure efficacy
- Pathogenesis or Lethality
- Communicability
- Morbidity
- Mortality
- Infectious or Lethal Dose
- Incubation Time
- Economic Impact

PTA

- Intel
- Agent acquisition
- Production capacity
- Dissemination efficiency
- Source strength
- Population Exposed

Population Exposure Estimates

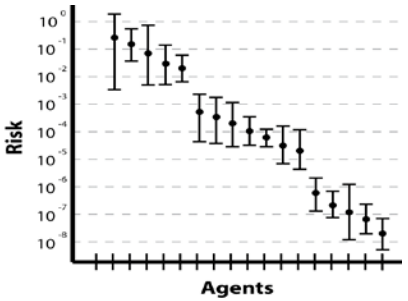
Exposure (CFU)	Column 1 All people are indoors	Column 2 All people are outdoors	Column 3 Baseline scenario: 90% of (Column 1) + 10% of (Column 2)	
≥ 5	5,000 – 10,000	10, 000 – 20,000	20,000 – 30,000	Population (people)
	0 - 5	5 – 10	10 -20	Plume Area (km²)
≥ 10	5,000 – 10,000	10, 000 – 20,000	20,000 – 30,000	Population (people)
	0 - 5	5 – 10	10 -20	Plume Area (km²)
≥ 30	5,000 – 10,000	10, 000 – 20,000	20,000 – 30,000	Population (people)
	0 - 5	5 – 10	10 -20	Plume Area (km²)
≥ 50	5,000 – 10,000	10, 000 – 20,000	20,000 – 30,000	Population (people)
	0 - 5	5 – 10	10 -20	Plume Area (km²)
≥ 100	5,000 – 10,000	10, 000 – 20,000	20,000 – 30,000	Population (people)
	0 - 5	5 – 10	10 -20	Plume Area (km²)

MCM (HHS BARDA)

- Medical Countermeasure efficacy (pre. vs. post. vs. treatment)
- Pathogenesis
- Communicability/transmissibility
- Morbidity
- Mortality
- Infectious Dose
- Incubation Time

Public Health Impact

=> MTD



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Provides cross-validation of inputs and results.

NBACC Provides Scientific Support for Threat Characterization

Biological Threat Characterization Center (BTCC)

- Conduct threat and risk assessments
- Close key gaps in traditional biological agents
- Develop a strategy for engineered biological agents

National BioForensics Analysis Center (NBFAC)

- Designated lead national facility for bioforensic analysis

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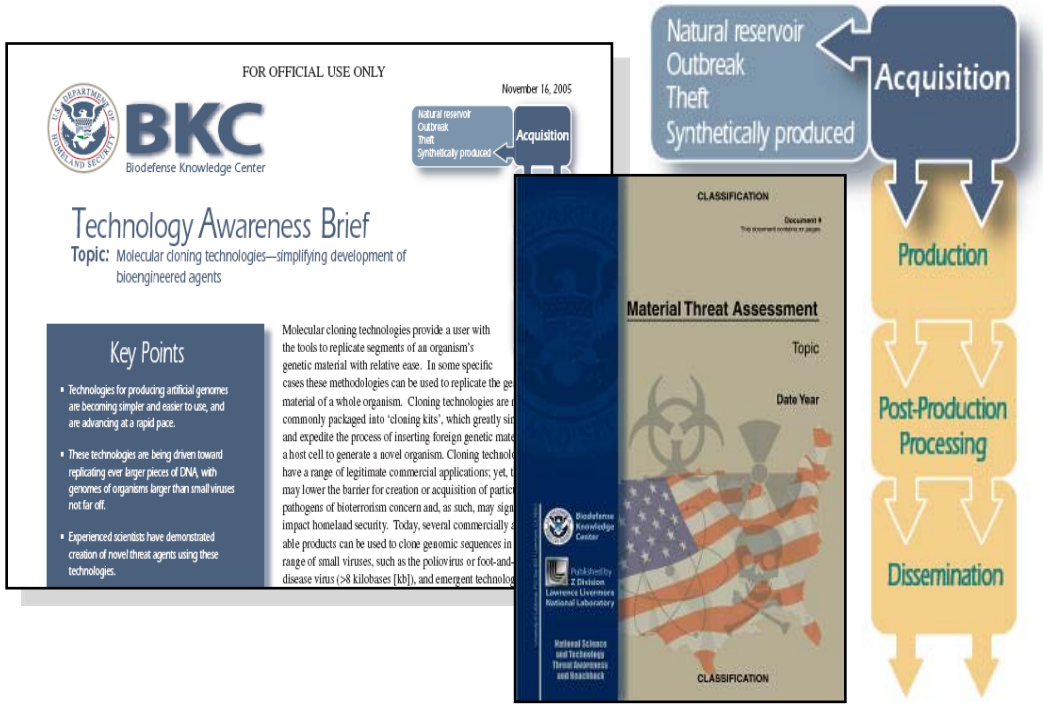
The Biological Knowledge Center (BKC) rapidly provides bio-threat management information & options



Analysis and operational support

- 24/7 S&T reachback for DHS National Operations Center
- tailored in-depth analysis of biodefense issues

Knowledge discovery tools

- data integration, analysis, and visualization
- deliver software pilots to DHS users to analyze, characterize, and understand biothreats

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Detection Paradigms and Timeline

FBADS
Food Biological Agent Detection Sensor

IBADS
Instantaneous Biological Agent Detection System

RABIS
Rapid Automated Biological Identification System

LBADS
Low-Cost Bio-Aerosol Detection Systems

Bioagent Autonomous Networked Detectors
BAND

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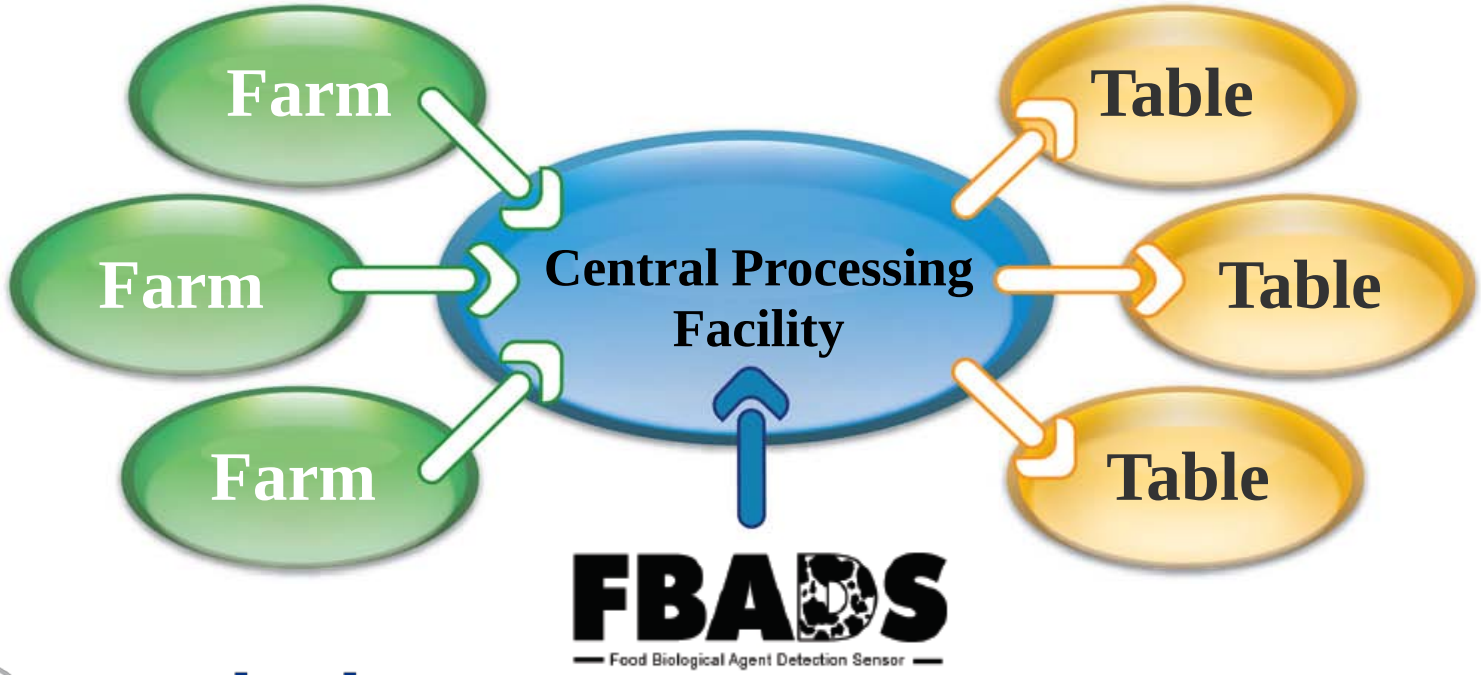
Food Biological Agent Detection Sensor

Goals

- Detectors for use in Central Processing Facilities of the food distribution system, with initial focus on liquid protein products
- Unit Acquisition Cost of $50K per Unit or Less
- Not impede current food distribution networks

Roadmap

- ***FY08:*** Validation and transition
- ***FY08:*** Demonstration of system flexibility – capability to detect other agents
- ***FY08:*** Pilot demonstration at a milk processing facility



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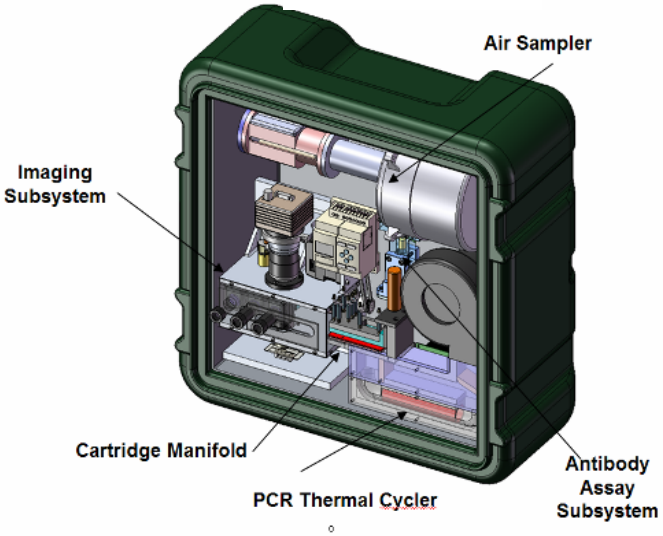
Rapid Bio-Detection Triggers & Confirmers

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**

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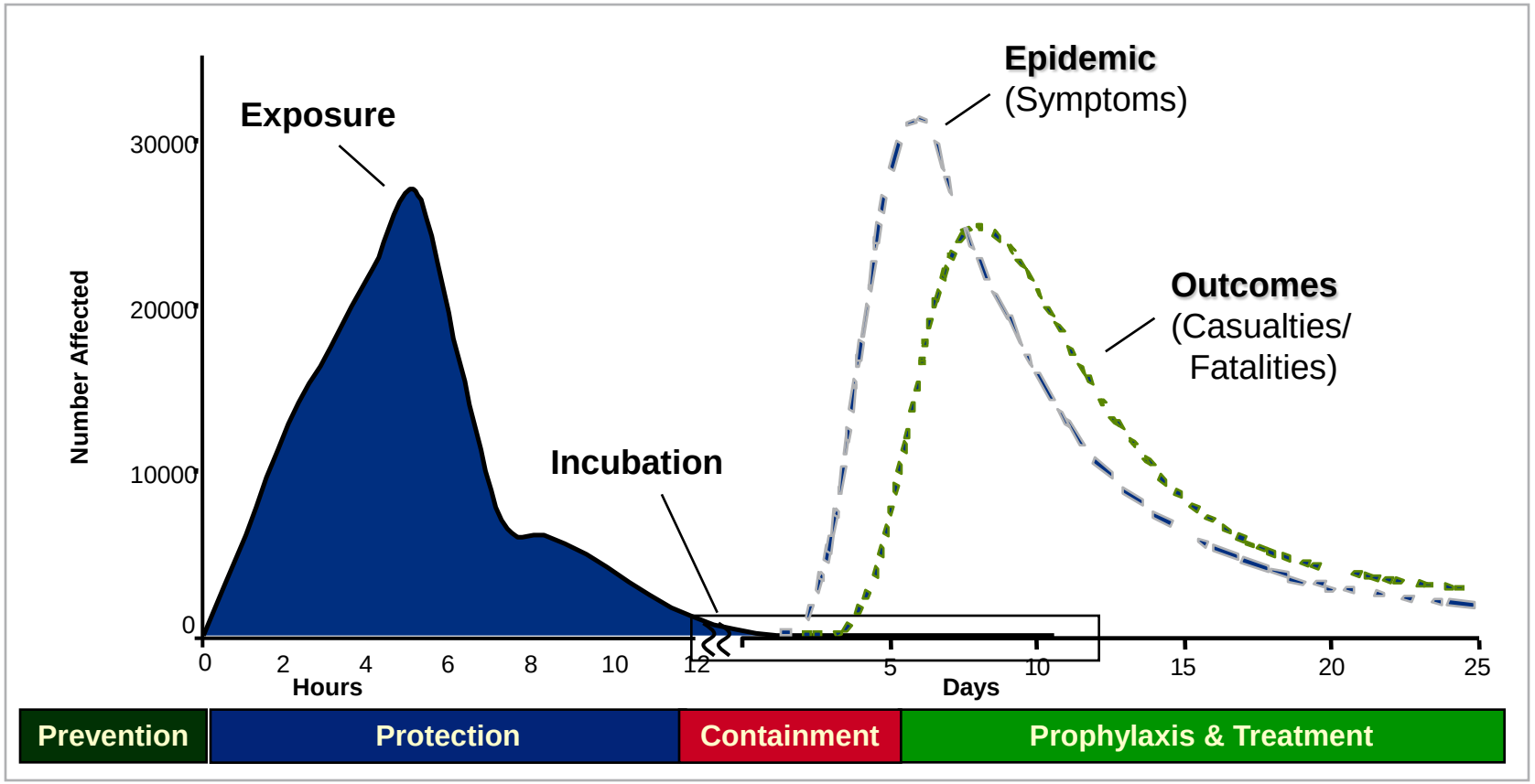
Early Detection & Treatment Play a Critical Role in the Biodefense Strategy



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Aerosol Biothreat Agent Environmental Monitoring

Gen 1 BioWatch (FY03)

- Operating in > 30 cities
- Detect in 12-36hrs
- Over 3M assays without a false positive

Gen 2 BioWatch enhancements (FY05-07)

- 4x increase in collectors in top 10 threat cities
- Critical transportation hubs and special events

Gen 3 BioWatch (FY09-12)

- Fully autonomous, analyzes at same site it collects – 3 to 6 times daily
- Cover a major portion of US population
- Detect a smaller attack than Gen 1
- Per unit operational cost < 25% of current system

Current BioWatch collects air samples & analyzes them in LRN lab

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R&D to Develop Next Generation Detection Systems and Assays

Diversify Engineering Challenge

- *Autonomous Multiplexed Micro-fluidic PCR*

Diversify Risk in Two Dimensions

Diversify Scientific Challenge

- *Broadband Approaches for Sequence Diversity*

Gen 3 Detection Systems

- Fully autonomous
- 20 agents (bacteria, viruses, toxins)
- Analyze every 3-6 hrs
- Better sensitivity & specificity than current BioWatch
- Per unit operational costs < 25% of current BioWatch

Major milestones/deliverables

FY05: Estimated laboratory feasibility

FY06: Develop and test lab prototype

FY07: Develop and test field prototype

FY08: Phase 3X development

FY08: DT&E field test

FY09: Transition to OHA; OT&E

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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

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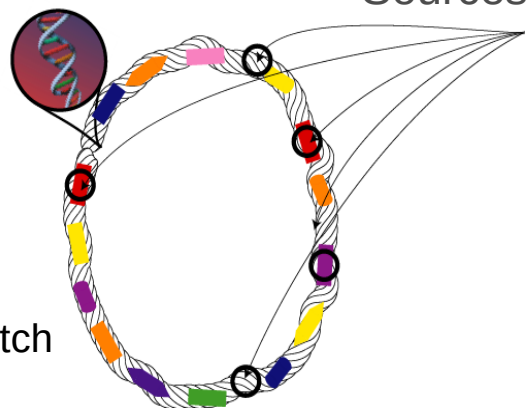
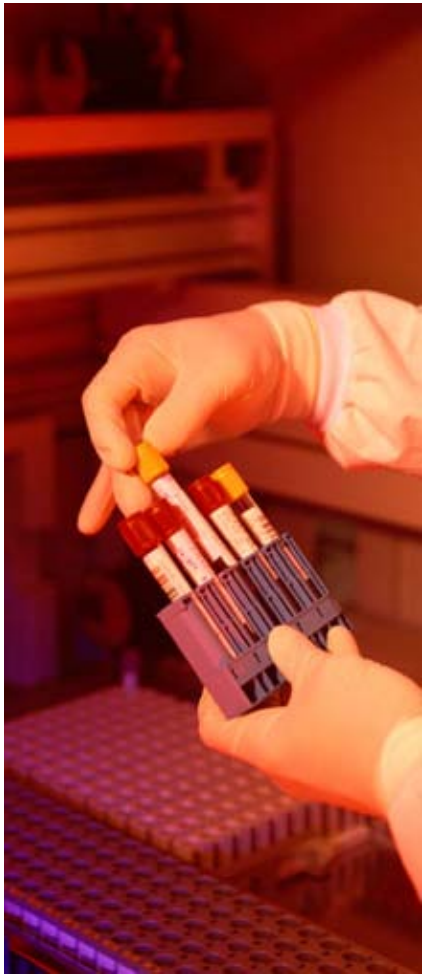
R&D to Develop Validated, Ultra-High Specificity Bio-Detection Assays

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

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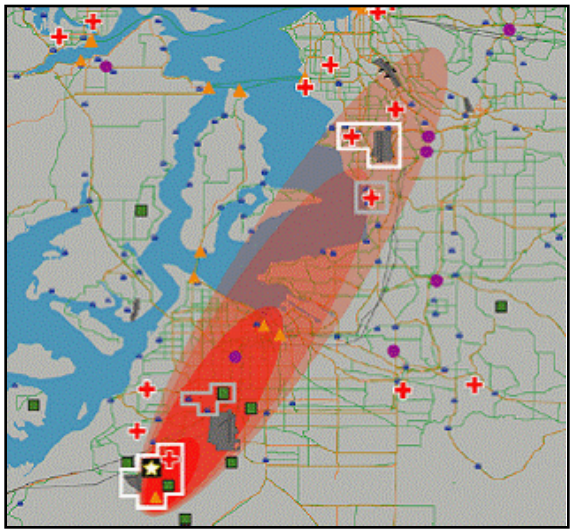
Systems Approaches & Decision Tools to Rapid Response & Recovery



Goals

- Demonstrate systems approached to large scale urban decontamination & recovery
- Develop improved operational tools to support response & recovery

Roadmap

FY07: share results of Airport Restoration Demo thru a series of workshops

FY07: initiate wide area restoration demo (joint effort with DTRA & Seattle)

FY08: guidelines & protocols for bioagent sampling

FY09: 'demonstrate' wide area restoration

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Forensic Analysis to Support Attribution

Goals

- National Bioforensics Analysis Center (NBFAC) designated **lead facility for technical analysis**
- Use biological, physical and chemical analysis to **find out how and where agent was made**

Attribution forms the foundation on which deterrence rests – (HSPD-10)

Roadmap

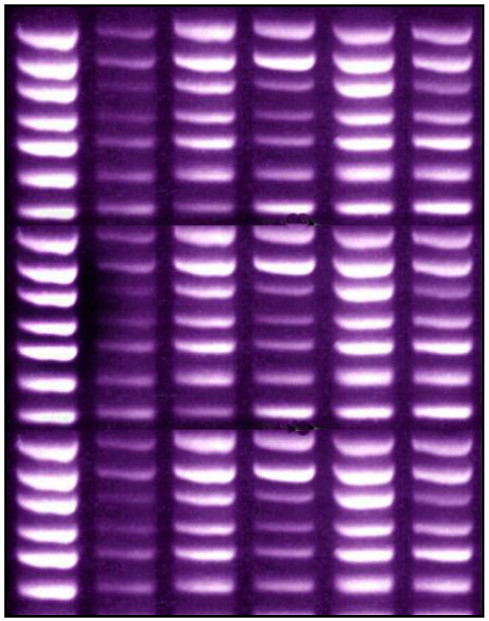
FY05: interim NBFAC operational and large operational case load

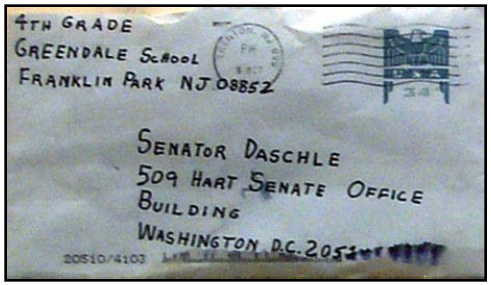
FY07: accredited by International Standards Organization (ISO-17025)

FY08: validated assays for top 20 agents

FY09: transition operations to the new NBACC facility

FY09: validated assays for the top 30 agents





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CBD agrodefense programs result from interagency planning focusing on foreign animal disease (FAD) mitigation

FAD Modeling

FMD outbreak decision support tools that enhance our ability to respond to outbreaks

- National scale epidemiogical, transportation system & economic impacts models
- Joint Modeling Assessment Center (USDA & DHS)
- Research & Policy for Infectious Disease Dynamics (NIH & DHS)
- National Institute for Mathematical & Biological Synthesis (NSF & DHS)

FAD Vaccines & Diagnostics

Characterize the effectiveness of current vaccines

Develop new vaccines that can speed the onset of immunity and distinguish infected from uninfected animals for foreign animal diseases.

- Foot & Mouth Disease (FMD; 10 major variants)
- Rift Valley Fever (FVF)

Deployment of high-throughput assays for detection of high consequence animal diseases

The S&T led interagency Joint Agro Defense Office provides coordination & oversight of the integrated agro-defense program formulated under the National Science and Technology Council

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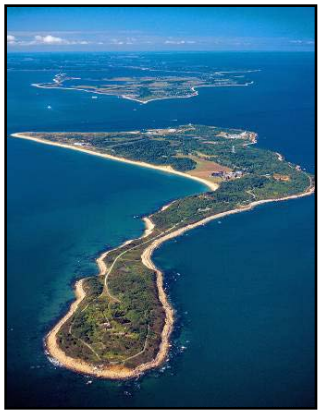
Agrodefense

Plum Island is an integral part of the DHS & USDA strategy



PIADC is responsible for **protecting the Nation against animal diseases** that could accidentally or deliberately be introduced into the country. R&D work is coordinated to address the needs of the Nation and is executed by leveraging the expertise of **DHS, USDA/ARS** and **USDA/APHIS**.

Net assessment of the FAD threat

- Animals as aerosol generators;
- Viral stability/survivability

Assays & diagnostics

- National and international validation;
- Enhance diagnostics capacity
- New bioforensics capability

Vaccines and therapeutics

- Improve on current vaccines;
- Explore vaccine alternatives;
- Develop anti-virals

New National Bio- and Agrodefense Facility (NBAF) preferred site selected to be Manhattan, KA

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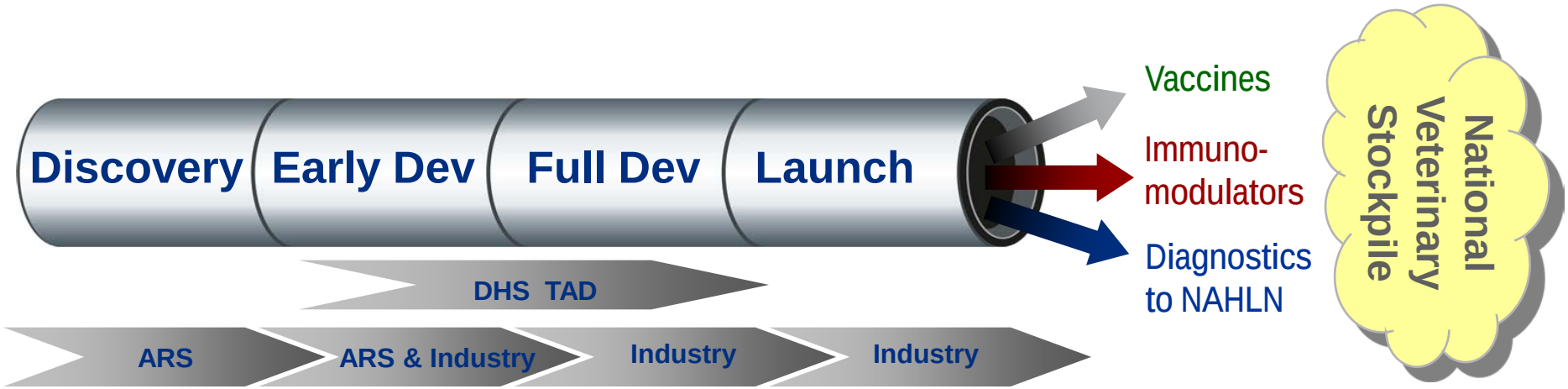
Defense Against Foreign Animal Diseases

Develop & transfer high-throughput diagnostics



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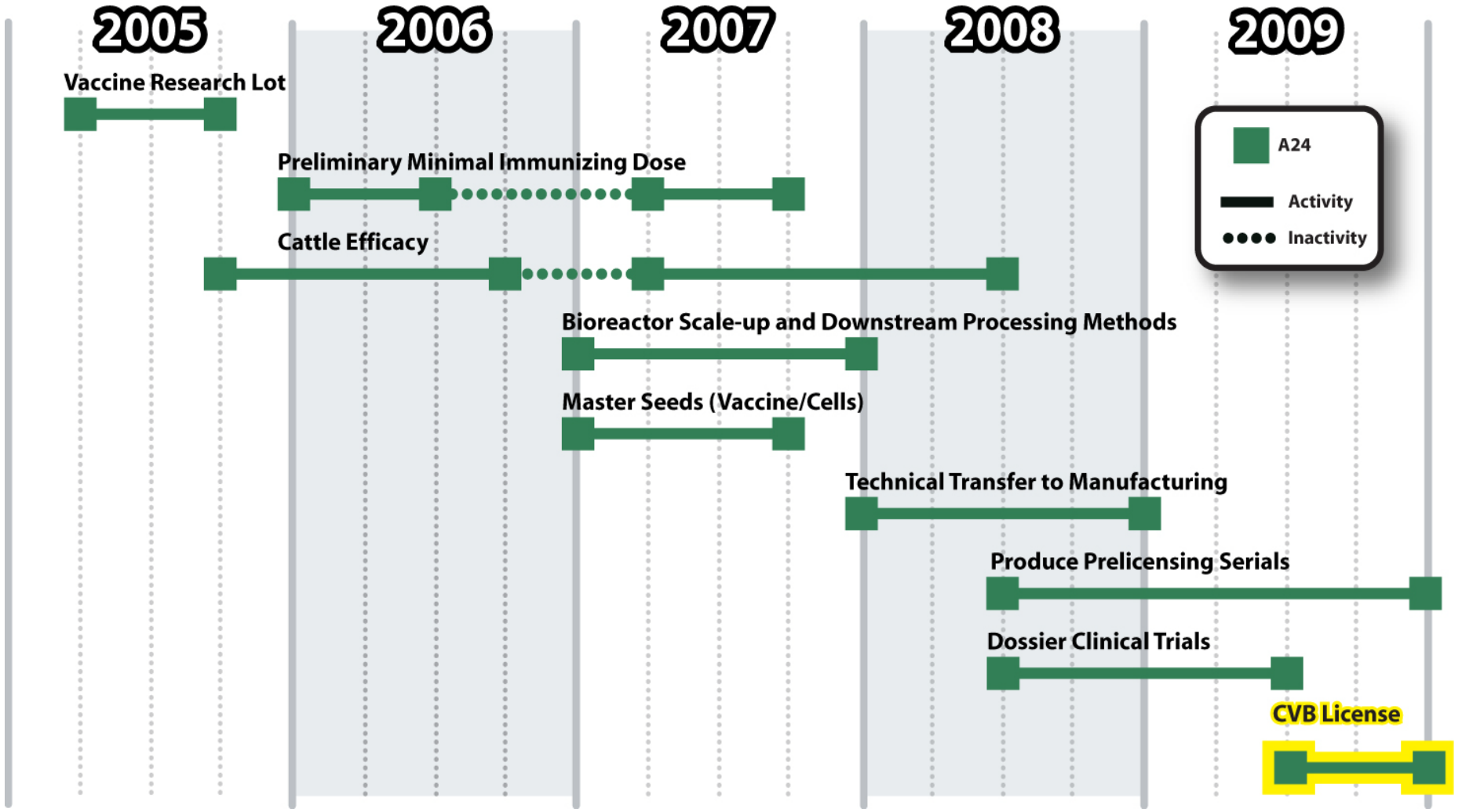
Developing Next-Generation FMD vaccines



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Chemical Defense Program Structure

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

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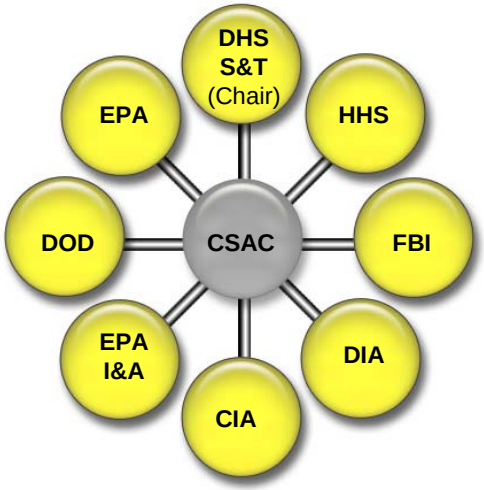
Chemical Analysis Provides Threat Awareness and Attribution



CSAC
Interagency Steering Committee

Goals

- Conduct threat risk assessments to inform national priorities
- Assess improved agent transport models to describe impacts of attacks on chem infrastructure
- Develop forensics tools and conduct operational analyses as required

Roadmap

FY06: interim Chemical Security Analysis Center (CSAC) established at ECBC

FY07: validated methodologies for G-agents

FY08: First Chemical Risk Assessment complete

FY08: validated methodologies for V-agents

FY09: complete assessment of chemical dispersion models and down-stream impacts

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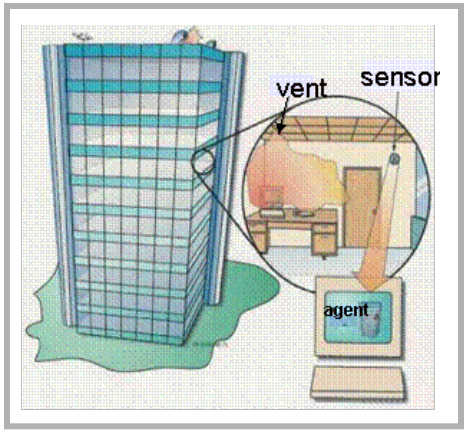
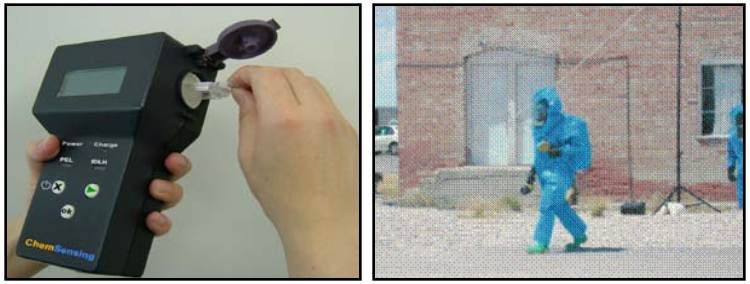
Detection is Developing Systems for Facility Monitoring & for First Responders



Facility Warning System (ARFCAM)



Responder Hand-held DetectionTool(LACIS)

Goals

- integrated protection systems for facilities
- rapidly deployable systems for special events and first responders
- detection of low vapor pressure chemicals on surfaces
- integrated CBRN detection architecture
- Commercialize & make available thru DHS Office of Grants & Training (DHS G&T)

Roadmap

FY04: transitioned the PROTECT subway system to commercial availability (DHS G&T)

FY05: develop a deployable system with ground & air components

FY06-07: lab prototypes of next generation facility warning & first responder detection systems

FY08: pilot integrated ChemBio architecture

FY09-10: fieldable prototypes of ARFCAM, LACIS

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Response & Recovery Develops Protocols & Tools to Rapid Recovery

Field Trial of Prototype Mobile Labs

Goals

- Demonstrated systems approaches to restoration of critical facilities
- Prototype fixed and mobile laboratory capability to support the recovery

Roadmap

FY07: demo mobile lab capability; prototype 3 fixed laboratories in high threat regions

FY08: prototype and transition mobile lab to the EPA; prototype 2 additional fixed labs

FY08: airport restoration table top exercise and restoration plan

FY09: airport restoration demo

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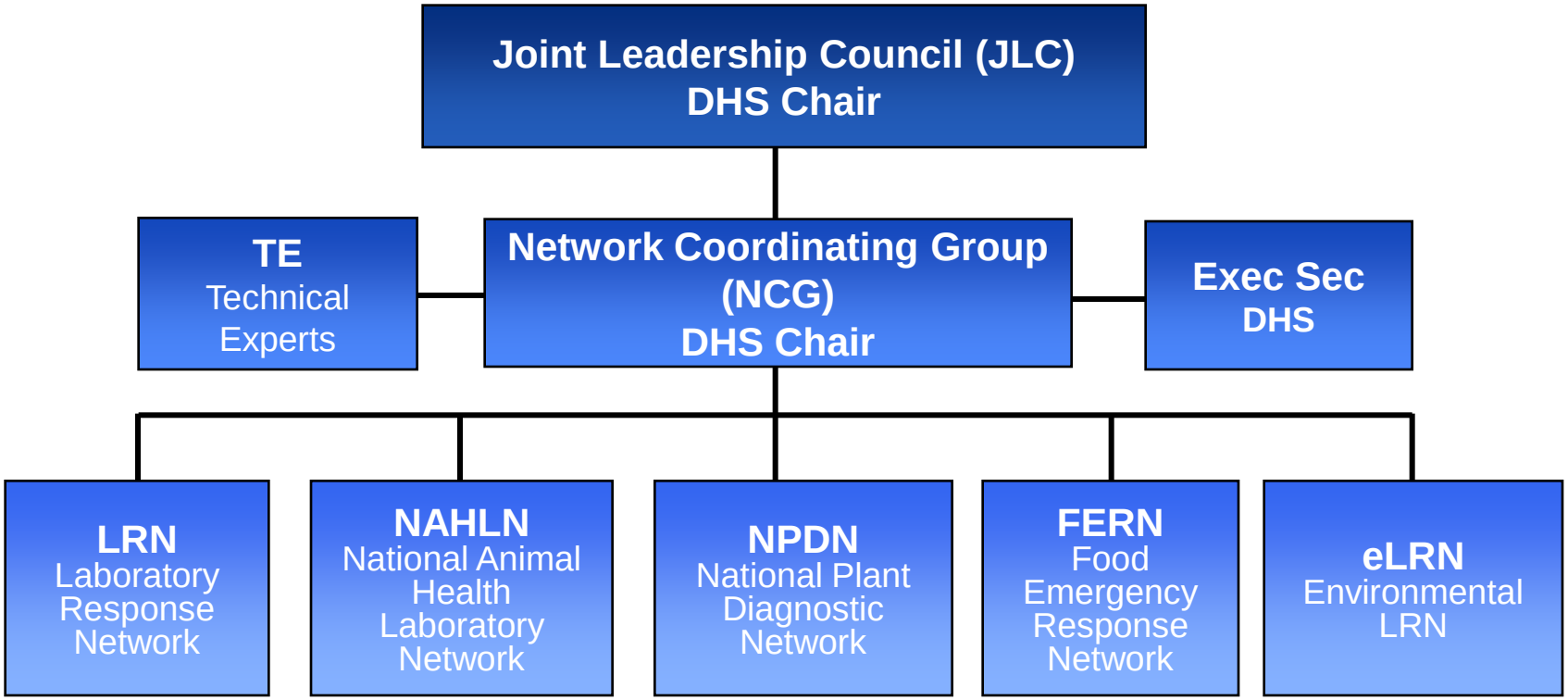
Integrated Consortium of Laboratory Networks (ICLN)



Key interagency players include **DHS, EPA, DoD, CDC, FDA, USDA, NIST, FBI, DOS,** and **DOE**

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Successful Transition of Major Programs to Our Customers

Gen 1, 2 BioWatch

Rapidly Deployable Chem Detection System (RDCDS)

BioWarning & IncidentQ Characterization System (BWIC)

BIOLOGICAL WARNING & INCIDENT CHARACTERIZATION
BWIC

Mobile Chemical Lab (PHILIS) to EPA

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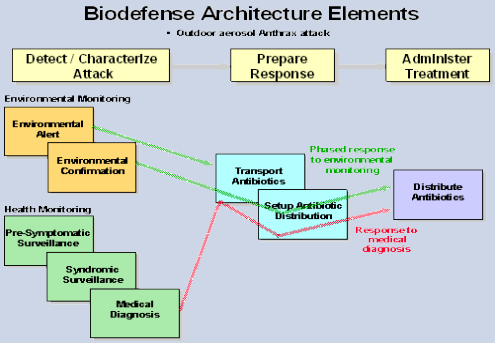
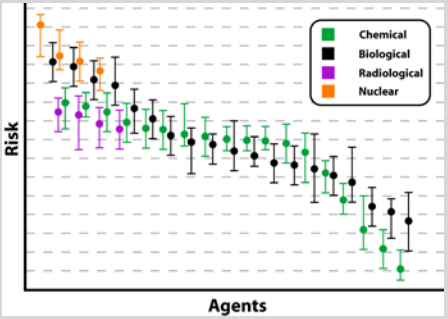
Successful Transition of Major Products to Our Customers

1st Bio Net Assessment



CBRN Risk Assessments



Category A Characterization Assays for Bioforensics

Interim Plan for Wide Area Bio Restoration

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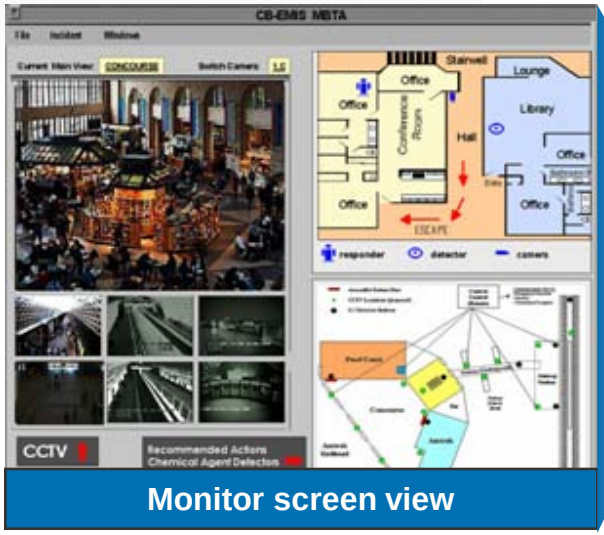
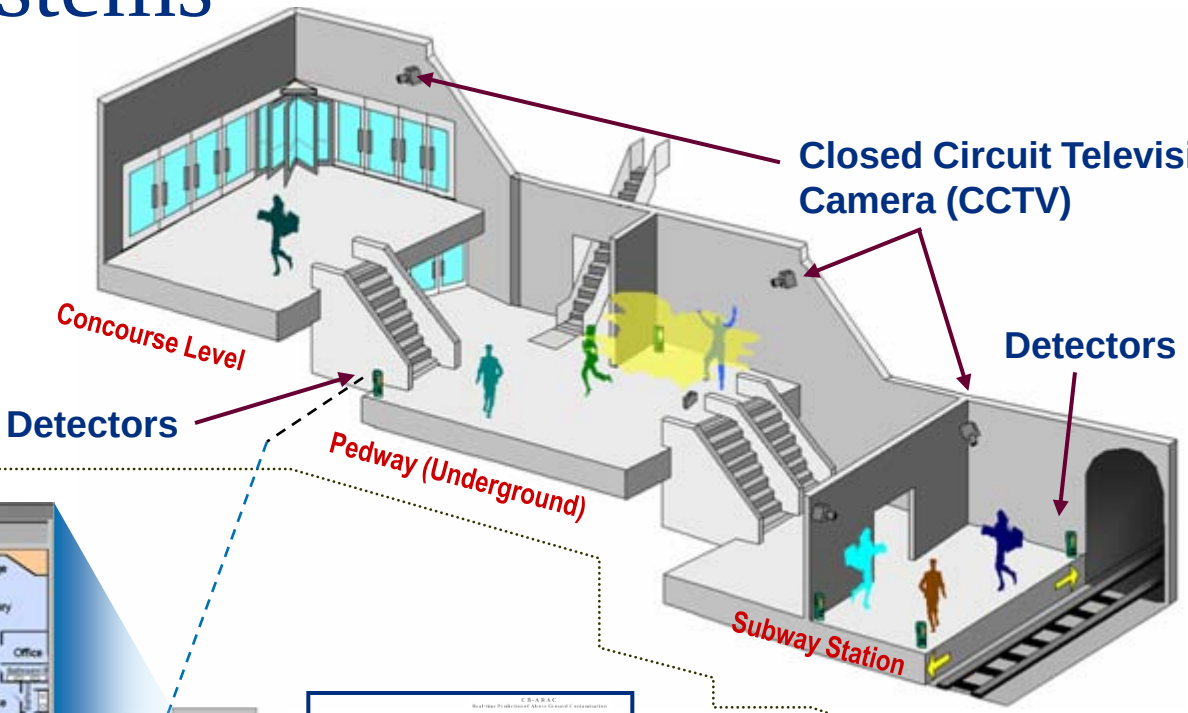
PROTECT: Chemical Early Warning System for Transit Systems

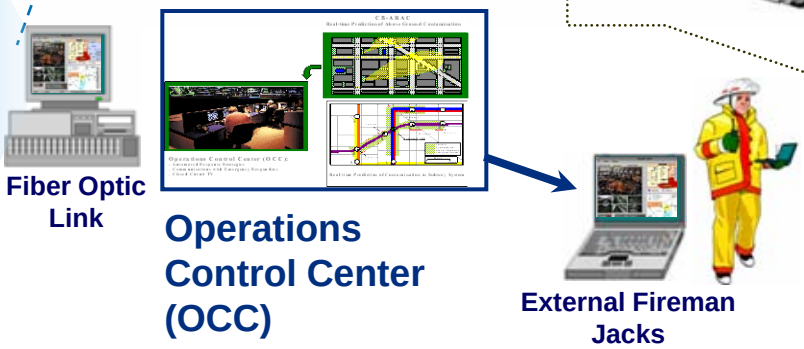
Demonstration completed 2003

This program has transitioned and is an allowable expenditure under the Transit Security Grants Program



Monitor screen view





Fiber Optic Link

Operations Control Center (OCC)

External Fireman Jacks

Homeland Security

Challenges

- Rapid Detection of the Unknown Threat

- Engineered
- 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

Homeland Security