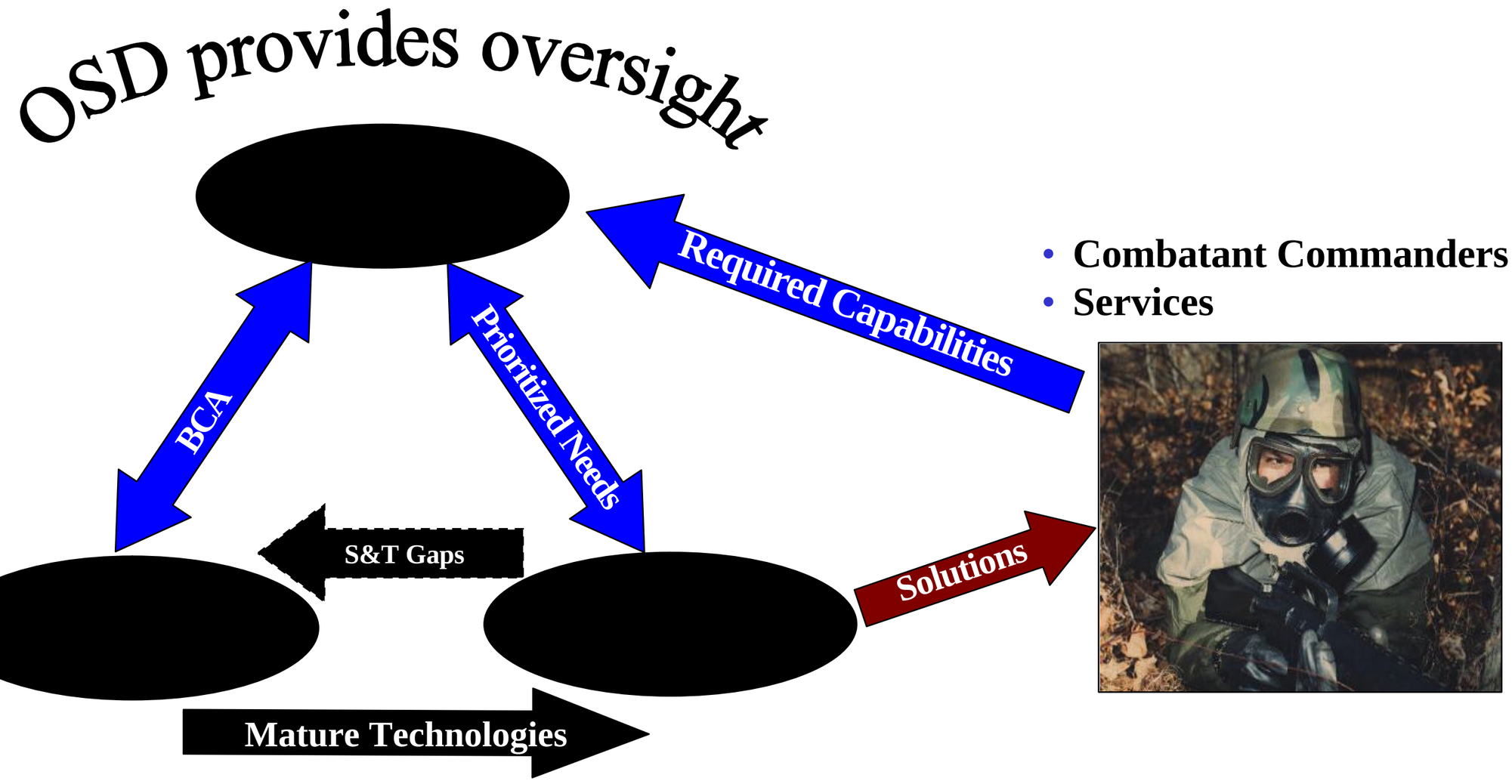
Chemical/Biological Defense
S&T Program Overview

Briefing for Industry

Dr. Chuck Gallaway

6 April 04

JSTO responds to warfighter needs



- **Combatant Commanders**
- **Services**

Vision

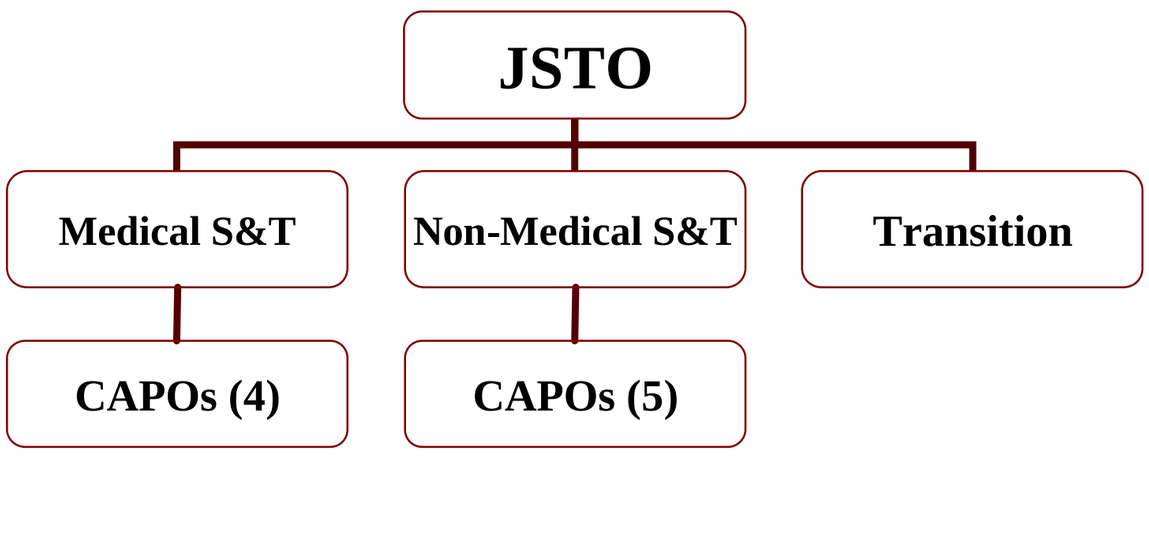
Develop and sustain a robust, agile, and flexible science and technology program to support DoD CB defense capability needs

Mission

- CB Defense Program Science and Technology
  - Research, demonstrate and transition CB technologies
  - Answer CB science questions
  - Maintain robust CB knowledge base
- CB Defense Program Financial Management

Enabling the Vision

CB S&T Management



- Management is separated from execution
- Capability Area Program Officers (CAPOs) are empowered and responsible for the integration of their business areas

We are maximizing performance

CB S&T Performers

Air Force | Army | Marine | Navy

Academia | FFRDC | Industry | International

National Labs

- Select the best performers
- Performers execute the S&T program
- Leverage Services to manage external performers

We are collaborating and cooperating

- Department of Homeland Security
  - Develop joint R&D roadmap
- Department of Health and Human Services
  - Develop joint R&D roadmap
- DARPA
  - Role in the CB Defense S&T Program
- International
  - Establish CBDP international office
- Intelligence Community
  - Leverage efforts

We are focusing on products

- Align efforts to prioritized capability gaps derived from the JRO-CBRN Baseline Capability Assessment
- Concentrate S&T investments and transitions to maximize returns
- Encourage innovation and raise acceptable risk threshold
- Assure S&T transition to the JPEO

Threats

- Threat is evolving despite non-proliferation initiatives
  - Nature of the Threat: State → non-State
  - Chemical Threat: Classic → NTA
  - Biological Threat: Classic → Engineered

- Military operators now must consider Toxic Industrial Materials

- Area of operational interest has expanded from the traditional battlespace to include all components of global projection

Program structure

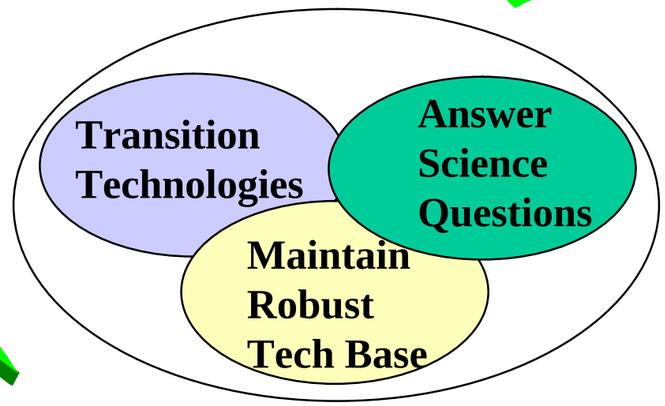
- Three major areas
  - Medical
  - Non-Medical
  - Transition

Medical S&T Efforts

Pretreatments

Diagnostics

Emerging Threats/ Special Programs

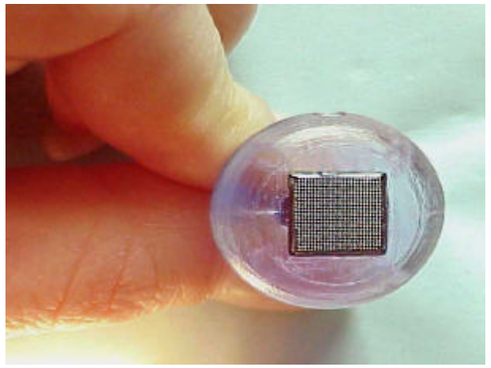


Therapeutics

Provide medical solutions for military requirements to sustain and protect the force in CB environment

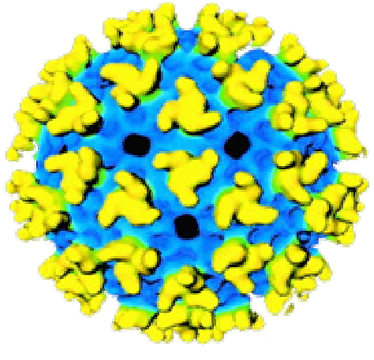
Pretreatments

Bacterial Vaccines

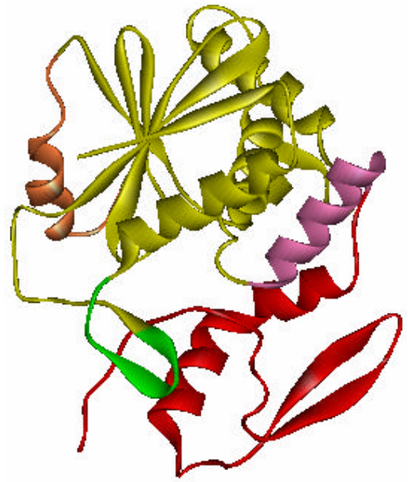


Alternative Vaccine Delivery Methods

Viral Vaccines



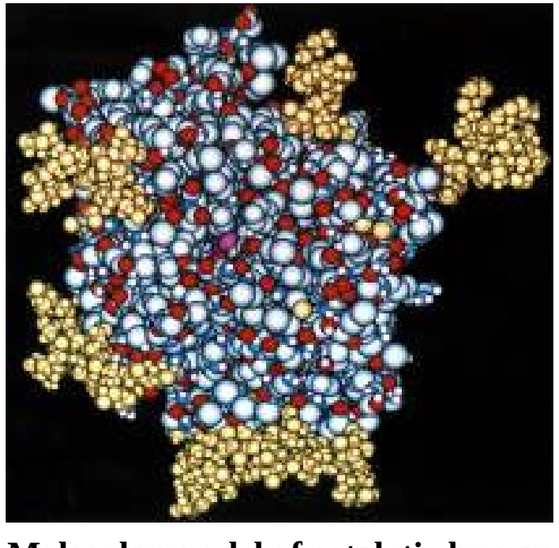
Packaged VEE Replicon Particle with Ebola or Marburg Virus genes



Toxin Vaccines

Ribbon diagram of recombinant A-subunit of Ricin Toxin Vaccine Candidate

CWA Pretreatments



Molecular model of catalytic human Butyrylcholinesterase bioscavenger

Pretreatments

Goal: **To support development of FDA-licensed vaccines and improved medical countermeasures against bacteria, viruses and toxins and chemical warfare agents**

Major Technical Challenges

- **Development of a "next generation" FDA-licensed plague vaccine and an improved generation-after-next anthrax vaccine**
- **Identification and evaluation of an efficacious and safe pretreatment to counter cyanide toxicity**
- **Improved modeling accuracy and reliability**
- **Complete pre-clinical development of the recombinant F1-V fusion protein plague vaccine candidate**
- **Develop a FDA licensed Venezuelan equine encephalitis (VEE)/WEE/EEE vaccine constructs appropriate for combination into a single vaccine and**
- **Develop medical countermeasures to VEE**
- **Develop FDA-licensed vaccines against Marburg and Ebola viruses**
- **Evaluate alternatives to the injection of recombinant protein-based vaccines that result in mucosal and systemic immunity to selected BW agents**
- **Produce a safe and effective vaccine candidate for protection against aerosol exposure to ricin toxin**
- **Enzyme-based pretreatments for nerve agents**

Pretreatments

FY04 Accomplishments

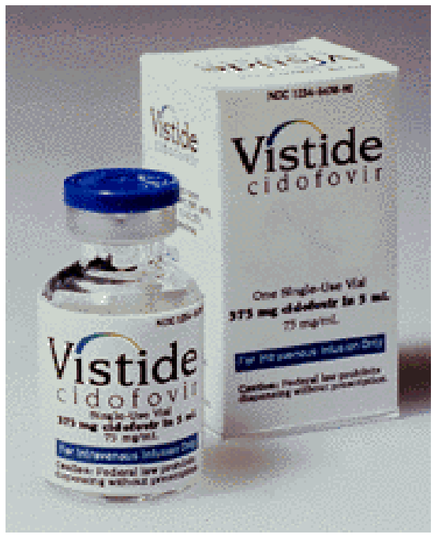
- Plague Vaccine: Milestone A approval by Advanced Developer
- Anthrax Vaccine: Transitioned recombinant Protective Antigen (rPA) based anthrax vaccine to VaxGen for development under the NIAID Biodefense Program
- Venezuelan Equine Encephalitis Vaccine: Demonstrated that a single component vaccine, based on the V3526 candidate, could protect against all other major biotypes of VEE

FY05 Planned Program

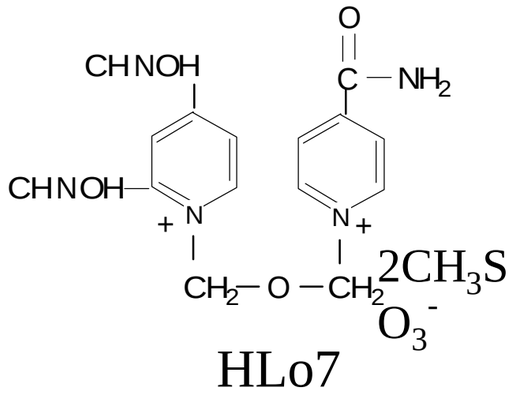
- Produce multi-agent filovirus vaccines and test with combinations of adjuvants and delivery methods in relevant animal models
- Evaluate immune modulators for use as adjuvants in protein and DNA vaccines
- Continue to advance computational chemistry for design of protein vaccines against toxin agents
- Continue development of catalytic bioscavengers as pretreatments against nerve agents

Therapeutics

Biological Therapeutics



Chemical Therapeutics



HLo7

ATNAA

Atropine

2PAM

Therapeutics

Goal: To support Development of products leading to the improved medical countermeasures to Select Agents; promote development of FDA-licensed antimicrobial and therapeutic products

Major Technical Challenges

- **Identification/characterization of candidate therapeutics using *in vitro* laboratory and animal models and demonstrating their capability to reduce morbidity in animals exposed to predicted battlefield doses**
- **Development of an FDA approved treatment drug directed towards countering the effects of traditional nerve agents**
- **Development of a standardized or optimized methods for sulfur mustard (HD) treatment; define treatment guidelines and diagnostic instrumentation**
- **Development of medical countermeasures to inhaled CWA by testing *in vitro* and *in vivo* models for exposures**
- **Develop a FDA-licensed therapeutics against smallpox and other orthopoxviruses, filoviruses (Marburg and Ebola and toxins**
- **Demonstrate safe countermeasures to injuries caused by vesicant chemical agents**
- **Evaluate candidate broad spectrum oximes to replace the current oxime for nerve agent therapy.**

Therapeutics

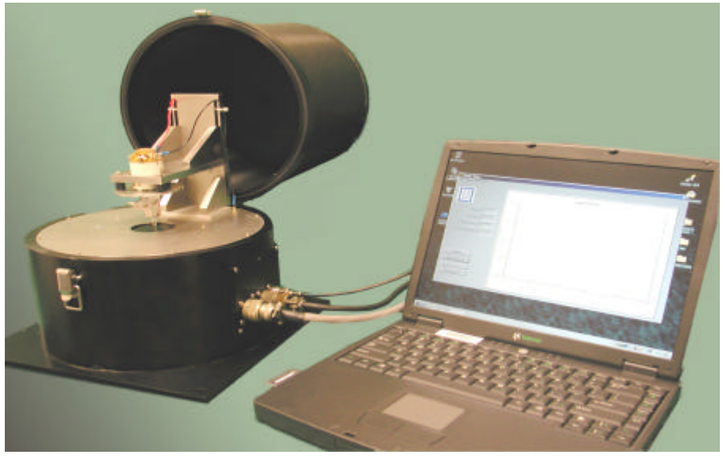
FY04 Accomplishments

- Demonstrated efficacy of gentamicin as a treatment for inhalational plague under the sponsorship of NIAD and FDA. The data will be used to support changes in the indicated uses of the antibiotics.
- Identified three potential oximes to replace the current oxime. These compounds have broader efficacy and can effectively treat all known nerve agents.
- Completed development/evaluation of a therapeutic that reduces edema and erythrema by >80% following sulfur mustard (HD) exposure. This is the first therapy for HD since HD was first used during World War I.

FY05 Planned Program

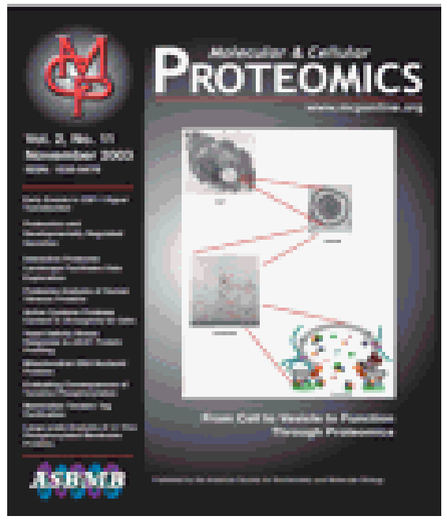
- Continue evaluation of leading oxime candidates; transition lead candidate to JPEO
- Continue evaluation of oral prodrug of Cidofovir

Diagnostics



Diagnostic Technology Assessment

Assay Development



Identification of Novel Targets

Research Test and Evaluation

Diagnostics

Goal: **To support promising new technologies and conduct investigations to determine military usefulness**

Major Technical Challenges

- **Production of diagnostic assays for multiple platforms meeting specific technical requirements; support new and existing technologies**
- **Identification of novel agent/host-specific markers that could serve as useful targets for the presence of/exposure to biological threats**
- **Testing of platforms and assays under field conditions**
- **Development of animal model systems enabling diagnostic assay validation testing**
- **Development of improved assays to include screening procedures and definitive analytical methods for verification of CWAs in biomedical samples**
- **Develop of a portable diagnostic system; current systems are not easily deployable; JBAIDS requires S&T support for full deployment**
- **Effective biomonitoring of CWAs in clinical specimens**

Diagnostics

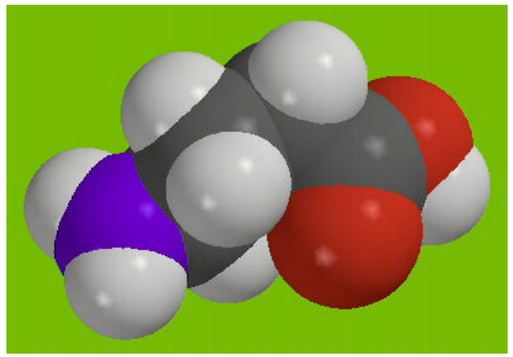
FY04 Accomplishments

- Transitioned Technical Data package for ≥30 assays to JPEO
- Developed techniques for DNA microarray-based detection platforms and prototype microarray array chips for *Bacillus anthracis*
- Evaluated host response markers for flu as possible interferents for BW agents (in monkeys after exposure to Venezuelan Equine Encephalitis)

FY05 Planned Program

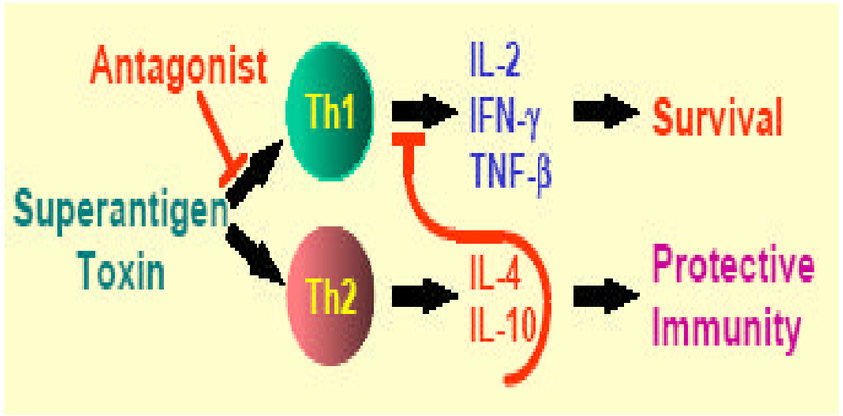
- Continue evaluation of new technologies, focusing on molecular microarrays
- Develop standardized validation package for assays
- Conduct multi-center joint-Service trial for two immunoassay platforms

Special Projects/Emerging Threats

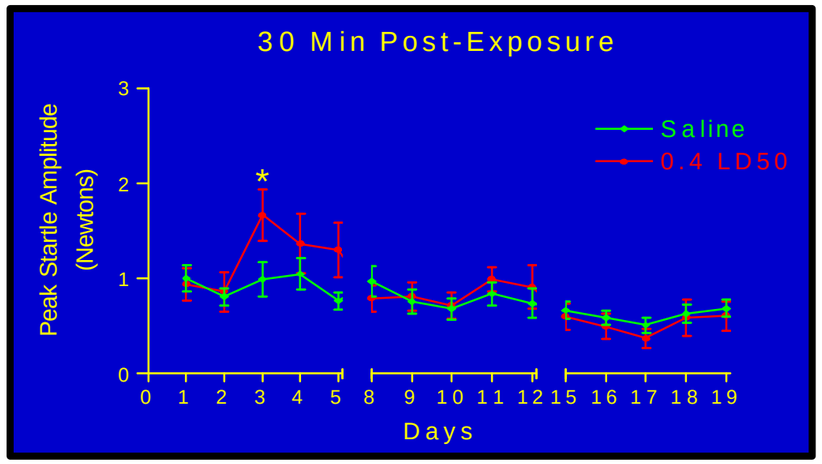


Non-Traditional Agents Countermeasures

Genetic Engineered Threats Medical Countermeasures



DARPA Transition



Low-Level CWA Exposure

Emerging Threats/Special Projects

Goals To Support

- **Exploration of systemic toxicity of low dose exposure(s) to chemical warfare agents (CWA); identify mechanisms of toxicity and determine the efficacy of medical countermeasures**
- **Determination of the toxicity and effectiveness of medical countermeasures to Nontraditional Agents**
- **Research related to information and identification of genetically engineered threats**

Major Technical Challenges

- **Reduce error in current human health risk assessment prediction for CW exposures. Determine low level exposure/time/effect relationships**
- **Enable the development of medical countermeasures against non-traditional nerve agent (NTA) intoxication. Identify and characterize compounds or medical strategies using laboratory and animal models that demonstrate the ability to prevent, interrupt, or terminate the action of NTAs.**

Emerging Threats/Special Projects

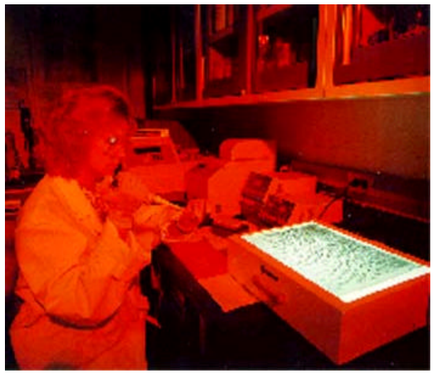
FY04 Accomplishments

- Completed inhalation data in animal models on the toxicity effects of low level chemical agents. Applied results to refining estimates of operational human health risk assessments.
- Completed pharmacokinetic studies of candidate bioscavenger for protection against nontraditional agents in multiple animal models

FY05 Planned Program

- Evaluate efficacy of candidate medical countermeasures against nontraditional chemical warfare nerve agents
- Characterize emerging chemical warfare agents
- Complete assessment of short-term effects of low-dose VX exposure on behavioral tasks in non-human primates
- Design and implement computer-based tools for the sequence- and structure-based analysis of toxins and virulence factors

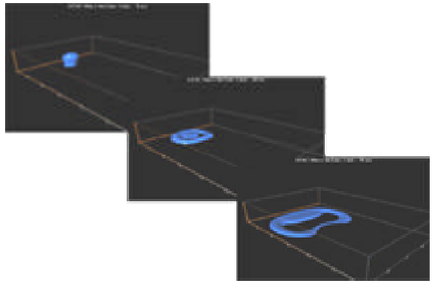
Non-Medical S&T Capability Areas



Supporting Science & Technology

Detection

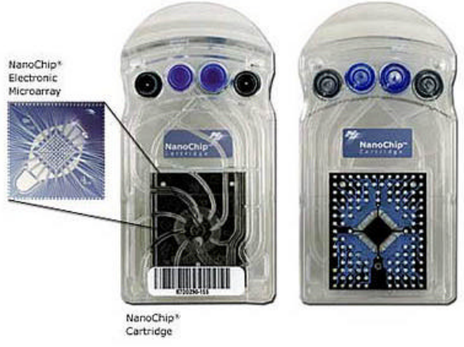
Protection



Modeling & Simulation

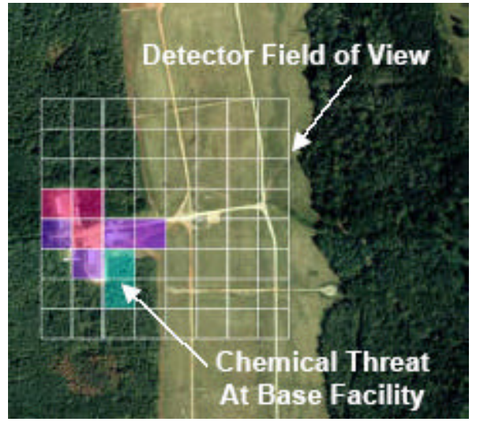
Decontamination

Detection

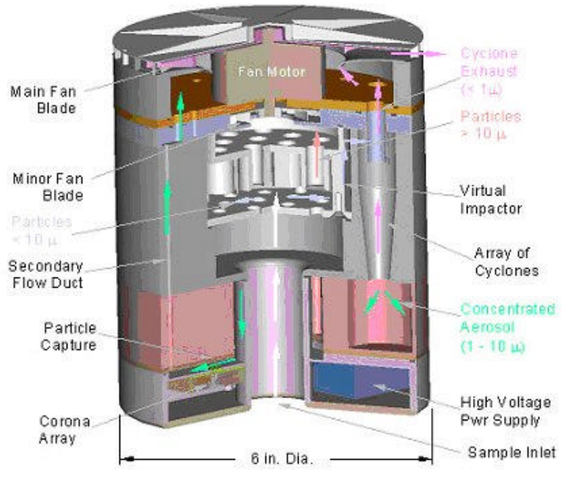


Biological Point Detection

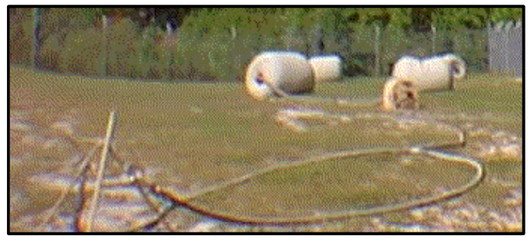
Biological Standoff Detection



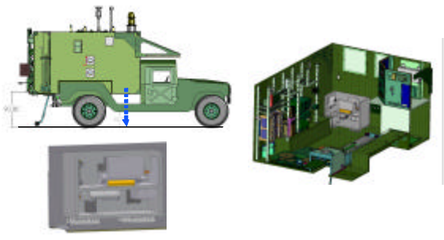
Chemical Standoff Detection



Integrated Point Detection



Water Detection



Integrated Standoff Detection

Detection
Goals/Challenges

- Reduced size, weight, and power requirements
- Integrate CB technology and/or platform
- Greater sensitivity, specificity stability, and fewer supporting reagents
  - Reduce false positive and negative alarms
  - Improve agent discrimination and quantification
  - Ambient biological background rejection
  - Genetic probe development
- Remote/early warning sensing
- Automated Sample processing

Detection

FY04 Accomplishments

- Flight test aerial reconnaissance breadboard systems, GPS map overlays of contaminant clouds
- Complete prototype build of a laser Raman-based system for surveying contamination on surfaces
- Develop multiplexed immunoassays to reduce logistic burden by 5X
- Assessed data from existing water quality monitoring in distribution networks to identify potential for compromises

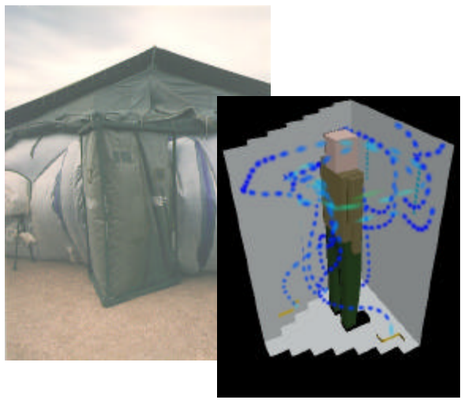
FY05 Planned Program

- Build prototype aerial reconnaissance, GPS map overlays of contaminant clouds
- Complete assessment of technologies to evaluate/verify post-decontamination of surfaces
- Initiate design and construction of an automated universal microarray biosensor for both medical and non-medical applications
- Reduce false alarm rate on fielded bio detection systems

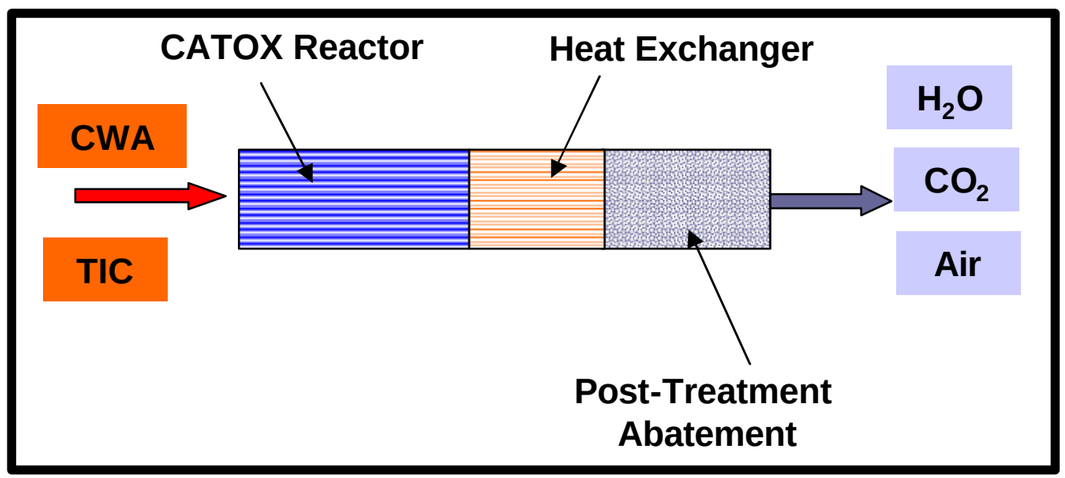
Protection

Clothing

Masks



Shelters



Air Purification

Protection
Goals and Challenges

- Goals:
  - Individual Protection Goal:
    - Reduce physiological burden of wear
    - Maintaining/improving high level of protection against CBR warfare agents/particles
  - Collective Protection Goal:
    - Reduce/improve size, weight, power and logistical (deployability) requirements of CP systems/filters
    - Improve protection capabilities against current and emerging threat agents (TICs)

- Major Technical Challenges:
  - Clothing/shelter made of reactive materials for (stable, and fast acting)
  - Maintaining toxic free areas for mobile and fixed sites

Air purification/shelter systems require tradeoffs (performance, user requirements, size, weight and power constraints, lifecycle)

Protection

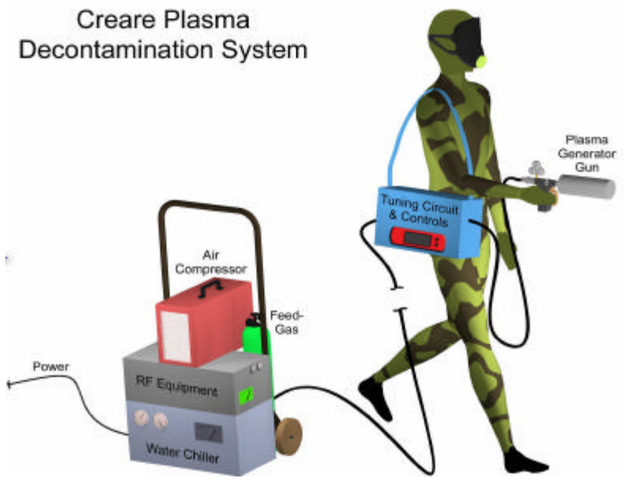
FY04 Accomplishments

- Completed testing of End-of-Service-Life Indicator films
- Demonstrated biocidal textile treatments
- Characterized adsorbents for removal of TICs and CWAs for regenerative filtration applications
- Developed expedient coatings (spray-on, etc.) to facilitate the quick chemical hardening of “safe” rooms

FY05 Planned Program

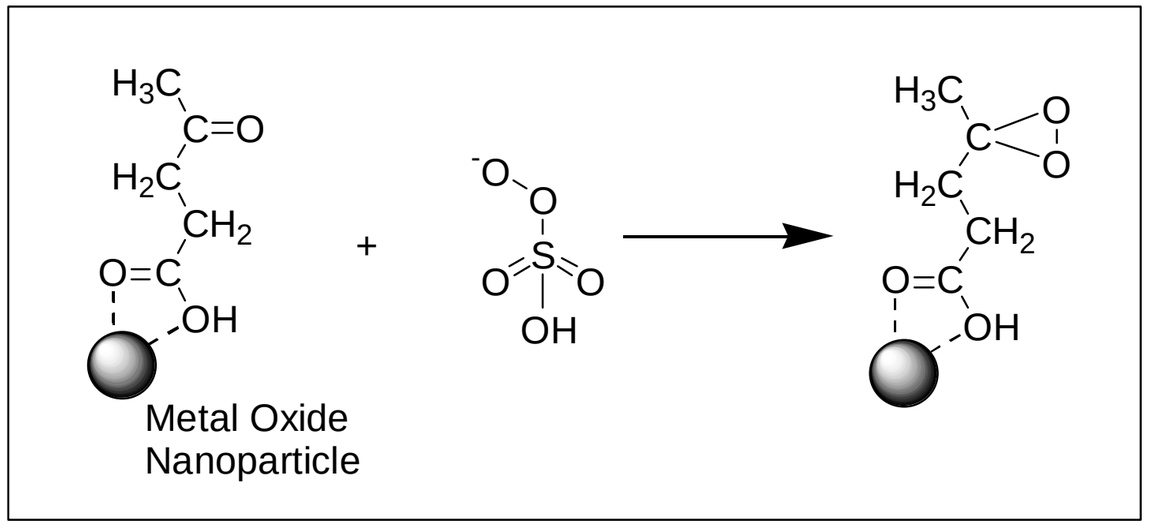
- Make final down-selection of candidate ESLI films and coating candidates
- Measure/optimize durability of biocidal treatments on fabrics
- Measure performance of catalyst in polymers fabricated using surface migrating compounds
- Evaluate candidate technologies applicable to next generation airlocks, hermetic closures and impermeable flexible barriers for shelter skins

Decontamination



Sensitive Equipment

Solution Chemistry



Solid Phase

Decontamination
Goals and Major Technical Challenges

- Goal: Develop technologies for **non-hazardous, non-resource-intensive decontamination** of equipment without degradation of the item being decontaminated in support of JRO-Sustain capabilities. Future systems will **minimize operational and logistical impact** of decontamination operations.
- Major Technical Challenges
  - Development of decontaminants that are:
    - non-corrosive, non-toxic, and environmentally safe
    - safe on sensitive equipment
    - able to decontaminate a broad spectrum of chem/bio agents
  - Development of decontamination systems that
    - effectively clean all surfaces and materials
    - reduce the manpower and logistics burden
    - effective in enclosed spaces and sensitive interiors (e.g., aircraft and tanks)

Eliminate toxic materials or their effects without performance degradation to the contaminated object—non-corrosive, environmentally safe, and light-weight

Decontamination

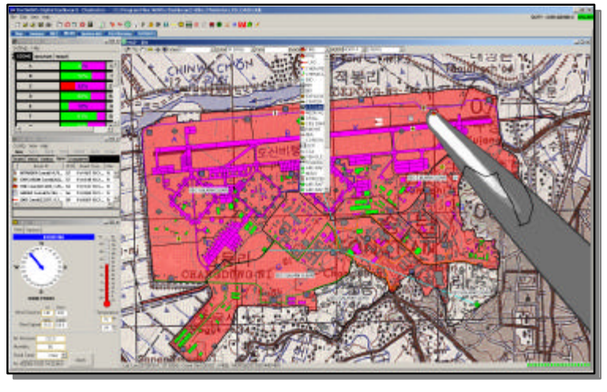
FY04 Accomplishments

- Develop environmentally friendly decontaminants based on commercial chemicals to replace existing fielded decontamination solutions
- Evaluate atmospheric plasma and thermal technology for interior decontamination
- Evaluate nanoparticles for decontamination systems

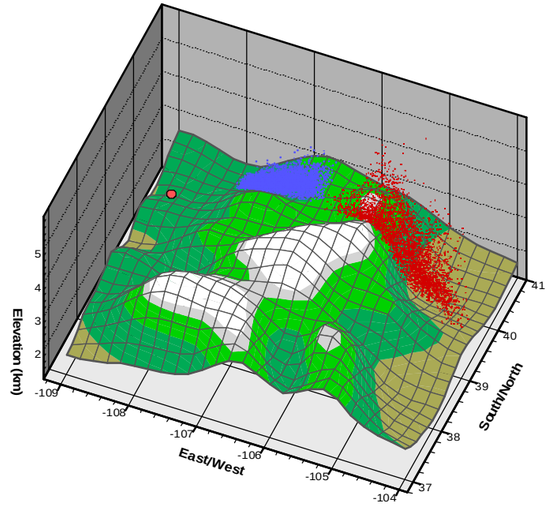
FY05 Planned Program

- Continue the testing of sensitive equipment cleaning solvents, expanding the test bed to include additional chemical and biological agents
- Develop and evaluate a solvent and reactive material wipe system to clean surfaces
- Evaluate stability of modified nanoparticles
- Quantify impact of new decontaminants on sensitive equipment surfaces

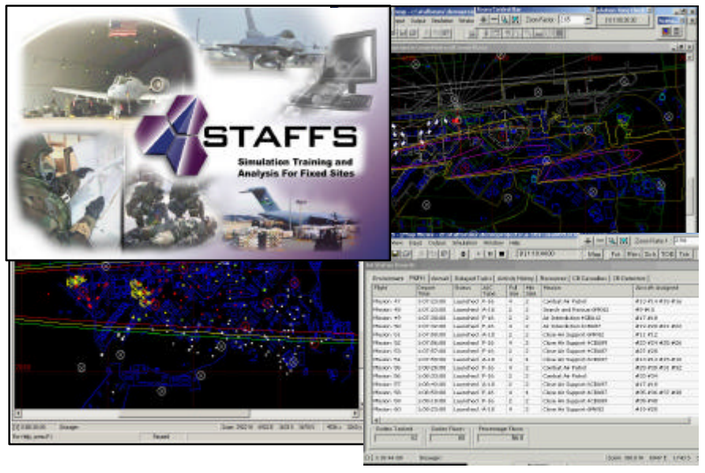
Modeling & Simulation / Battlespace Management



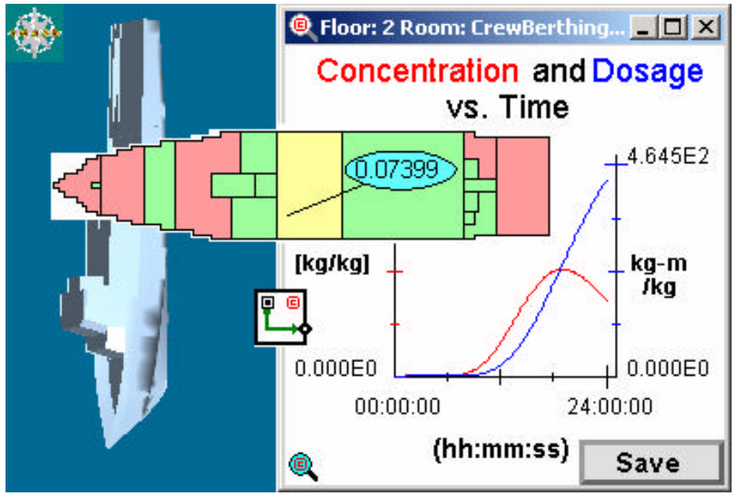
Battle Management



Environment



Planning, Training, and Analysis



Modeling & Simulation / Battlespace Management
Goals and Major Technical Challenges

Goal: To Support

- **Warfighter through C^{4}I networks and Information Systems**
- **Operational/national command authority with CBD environment decision systems; Materiel acquisition programs**
- **DoD level theater/warfare simulation efforts**
- **Materiel acquisition programs with Virtual Prototyping Systems (VPS) and Simulation Based Acquisition (SBA) tools and architectures**

Major Technical Challenges

- **CBRN hazards on complex, urban terrain and fixed sites**
- **Human effects, small unit behaviors and low level/long-term exposures in CB environment**
- **Developing engineering level models of CBRN defense equipment**
- **Virtual Prototyping Systems (VPS) for optimal CB equipment configuration and use**

Integrating/ interjecting CBRN effects/ops with C4I systems and combat/materiel simulations

Modeling and Simulation/Battlespace Management

FY 04 Accomplishments:

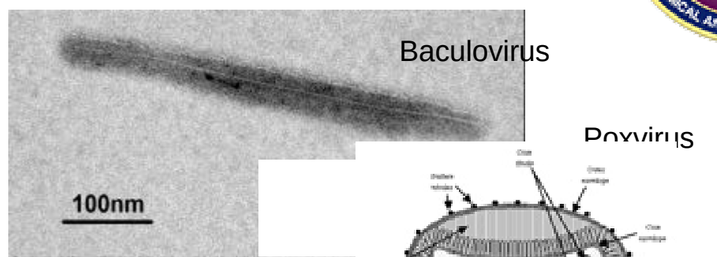
- Transition urban dispersion modeling to Joint Effects Model (JEM)
- Incorporate current weather into real-time dispersion model
- Redirect CB virtual prototyping system effort
- Focus bioinformatics modeling and simulation

FY 05 Planned Program:

- Develop acquisition decision tools
- Data sharing with Department of Homeland Security
- Develop capability to rapidly run simulations on battlespace management systems
- Initiate basic and applied research programs in bioinformatic programs

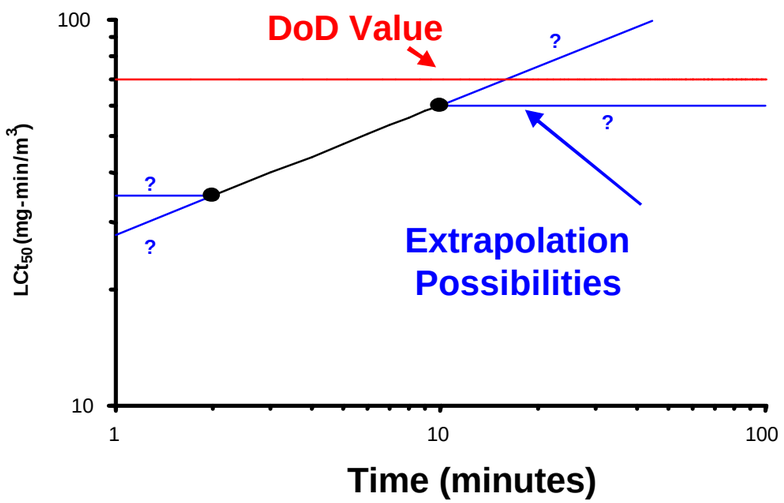
Supporting Science and Technology

Aerosol Technology

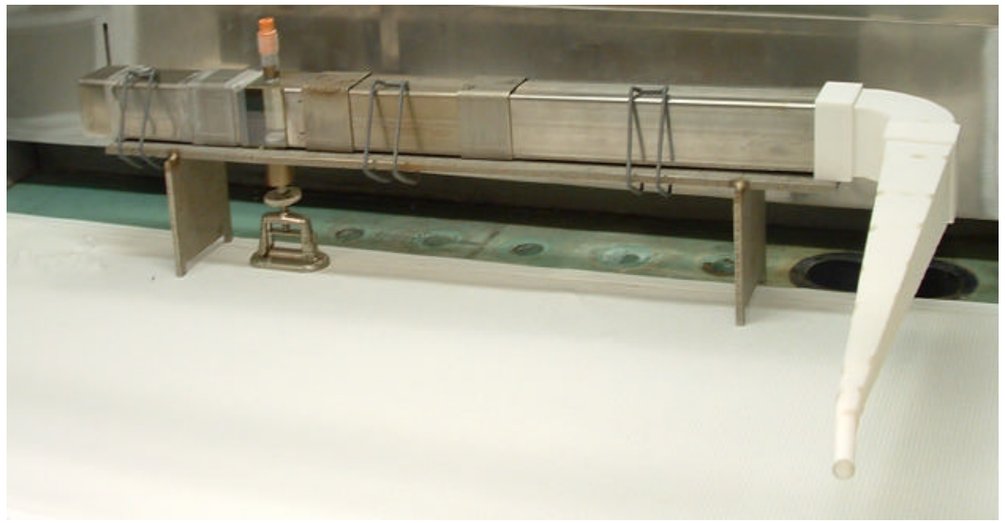


Virions of baculovirus, poxvirus and bacteriophage MS2 shown approximately to scale (see bar in photo).

CB Threat Agents and Simulants



Low Level Toxicology



Agent Environmental Fate

Supporting Science & Technology Goals and Major Technical Challenges

- Goal:
  - The primary goal of SS&T is to develop unique technologies in the following areas:
    - Aerosol technologies
    - Physical and chemical properties of chemical & biological agents
    - Simulant development and characterization
    - Toxicology studies for low-level exposure to CB agents
    - Fate of CB agents after release to the environment

- Major Technical Challenges:
  - Precise generation and accurate quantification of low-concentration CWA challenges
  - Model development and validation based on measured data

Supporting Science and Technology

FY04 Accomplishments:

- Complete evaporation studies on concrete; begin for asphalt and vegetation
- Develop methodology for scaling lab wind tunnel and field data
- Develop methodology to evaluate toxicity of emerging threat agents
- Investigate performance of novel aerosol collectors and concentrators, e.g., micro-HEPA

FY05 Planned Program:

- Complete agent fate scaling from lab and wind tunnel to the field.
- Validate test methodology for evaporation of agents on grass.
- Complete data collection for HD, GD, VX and thickened agents on soil and asphalt.
- Synthesize and characterize physical and chemical properties for agent-simulant correlation data base
- Establish final design of integrated cylindrical slit concentrator with cyclone. Characterize performance of electrostatic collector.

Transition Planning

INTEL

MEDICAL

LAW ENF

SENSORS

MEDIA

OPEN SOURCE

Transition Planning

GOALS/OBJECTIVES:

- **Provide technology transition plans for S&T and Advanced Concepts Technology Demonstrations (ACTDs)**
- **Plan Joint Warfighter Experiments (JWEs) addressing Combatant Commander initiatives in areas such as Biological Warfare Countermeasures Initiatives (BWCI)**
- **Provide the basis for Technology Transition Agreements (TTAs)**

Transition Planning

FY04 Accomplishments

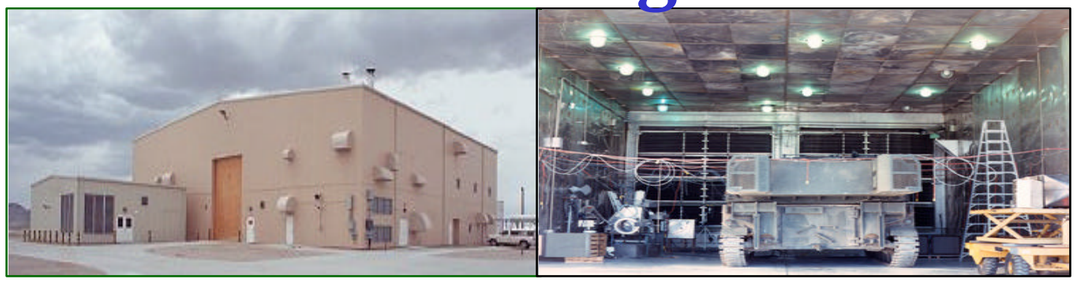
- Briefed CUGR ACTD to Breakfast Club
- Initiated CONOPS to support the CUGR ACTD
- Conducted a BWCI Fusion Cell/Force Protection Conditions workshop
- Initiated TTAs for candidate S&T technologies

FY05 Planned Program

- BWCI - Demonstrate STARNET/ fusion cell concepts
- CUGR ACTD - Initiate ACTD
- Initiate planning for FY06 CBRN ACTD
- Technology Transition Agreements documented for all non-medical and medical programs

Test and Evaluation

Testing



Test Chambers

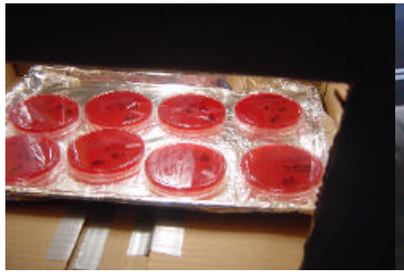
Test Ranges

Laboratories

Civil Support Teams

Evaluation

Analysis



Identification

Assessment

Test and Evaluation

GOALS/OBJECTIVES

- **Conduct Technology Readiness Assessments (TRA)**
- **Coordinate/oversee test capabilities, methodologies and infrastructure (CM&I) requirements**
- **Develop test criteria for S&T transitions/ACTDs**
- **Address test standards for CBRN survivability**
- **Coordinate tests to support JPEO mission requirements for Civil Support Teams (CSTs)**

Test and Evaluation

FY04 Accomplishments

- Completed Technology Readiness Assessment (TRA) of Point Bio Detector
- Identified critical shortfalls in current test CM&I
- Identified test capability needs for S&T technologies scheduled for TRAs in FY05-08
- Conducted military utility assessments of non-destructive evaluation technologies for CST support

FY05 Planned Program

- Conduct TRAs for CB filter life indicators, surface contamination detectors and collective protection technologies
- Continue efforts to improve test CM&I
- Identify test capability needs for S&T technologies for future TRAs
- Complete operational testing of CST CB technologies

Warfighter Enhancement

Warfighter Enhancement
GOALS/OBJECTIVES

- **Demonstrate mature technology to solve important military problems in ACTDs**
- **Execute joint tests on other than developmental hardware and accomplish operational assessments**

Warfighter Enhancement

FY04 Accomplishments

- RESTOPS - Publish ACTD Final Report
- CASPOD - Published Preliminary Demonstration Report and draft CONOPS for SPOD CB Defense and completed SPOD threat and vulnerability analysis
- JCDE (Project O49) - Publish Final Reports for Biological Agents on Surfaces; validated test, fixture, and analytical methods for Agent Fate; and conducted JSLIST in Elevated Wind Conditions field test

FY05 Planned Program

- RESTOPS - End Residual Support and Transition Activities
- CASPOD - Finalize ACTD Final Report
- JCDE (Project O49)
  - Conduct Warfighter Experiments
  - Publish Agent Fate Final Report and JSLIST in Elevated Wind Conditions

Anti-Terrorism/Force Protection

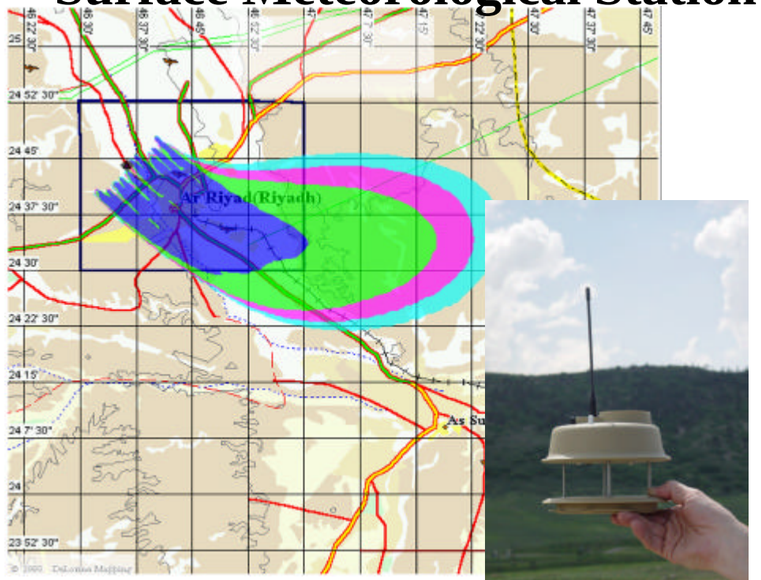
Surface Meteorological Station

95% 705 Km^2

50% 1,800 Km^2

25% 2,400 Km^2

5% 2,900 Km^2



Joint Service Installation Pilot Project

Contamination Avoidance of Military Mail

Anti-Terrorism/Force Protection
OBJECTIVES

- **Provide CB force protection equipment, concepts of operation and tactics/techniques/procedures for military installations**
- **Identify vulnerabilities in CB force protection**
- **Integrate real-time data to optimize CB sensor networks**

Anti-Terrorism/Force Protection

FY04 Accomplishments

- JSIPP: Completed fielding of CB detection equipment, CONOPS Development and exercises completed, and Quick Look Lessons Learned Report
- CAFMM: Completed Front End Requirements Analysis (FERA)
- SMS: Program initiation

FY05 Planned Program

- JSIPP: Transition program management to Services and issue Final Report
- CAFMM: Identify COTS equipment requirements, survey candidate mail handling facilities, and conduct initial CONOPS development seminars
- SMS: Develop sensor deployment guidelines and implement multi-season field test program

Bottom Line

- An agile S&T program to meet validated needs
- Best qualified performers pursue innovative solutions
- Effective technology transitioned to the user

Technology for the warfighter!