Department of Defense Chemical, Biological, Radiological and Nuclear Defense Program Overview



Colonel Debra Thedford, USA

Director, Chemical / Biological Defense Programs

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Outline

- Program Overview:
 - **✓** Program Restructure
 - ✓ Program Corporate Goals
 - **✓** FY05 President's Budget Submission
 - **✓** FY04 Congressional Adjustments
 - ✓ CB Defense Program Initiatives Fund
 - ✓ Other Initiatives
- Wrap-up and Questions



CBRN Defense Program Vision and Mission

ODATSD (CBRN Defense)

VISION

Combat Weapons of Mass Destruction through a Strong Chemical, Biological, Radiological, and Nuclear Defense Program

MISSION

Provide CBRN defense *capabilities* to effectively execute the National Strategy for Combating Weapons of Mass Destruction. Ensure all capabilities are integrated and coordinated within the Interagency community



CBRN Defense Program Strategic Environment

ODATSD (CBRN Defense)

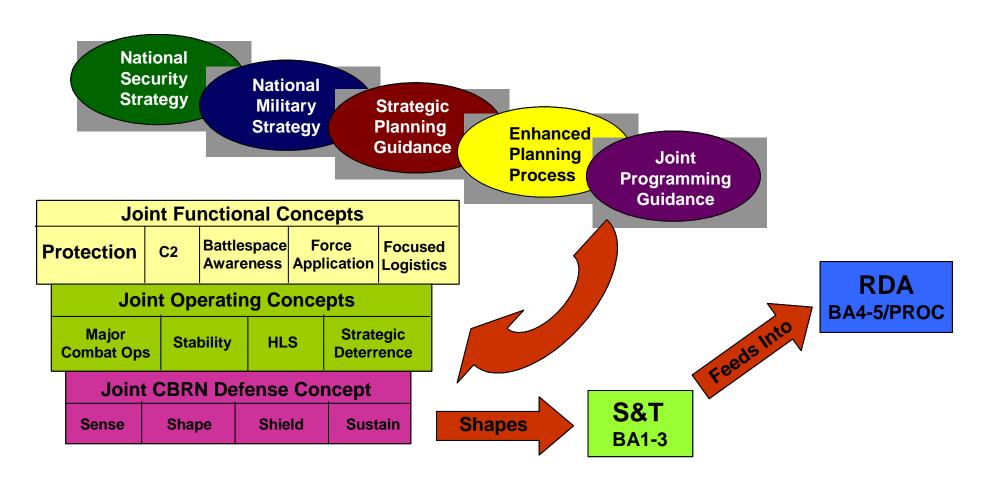
- Defense of the Homeland
- Global War on Terror
- DOD Role in Bioshield
- Proliferation of Weapons of Mass Destruction
- Challenge of Non-Traditional CBRN Agents
- Biosurety

"The greatest threat before humanity today is the possibility of secret and sudden attack with chemical, or biological, or nuclear weapons"

President George W. Bush Remarks at the National Defense University 11 February 2004



CBRN Defense Program Policy Drivers





Secretary of Defense's FY05 Priorities

- Successfully Pursue the Global War on Terrorism
- > Strengthen Combined/Joint Warfighting Capabilities
- Transform the Joint Force
- Optimize Intelligence Capabilities
- Counter Proliferation of WMD
- Improve Force Manning
- New Concepts of Global Engagement
- Homeland Security
- Streamline DOD Processes
- Reorganize DOD and USG to Deal with Pre-War Opportunities and Post-War Responsibilities



Program Restructure

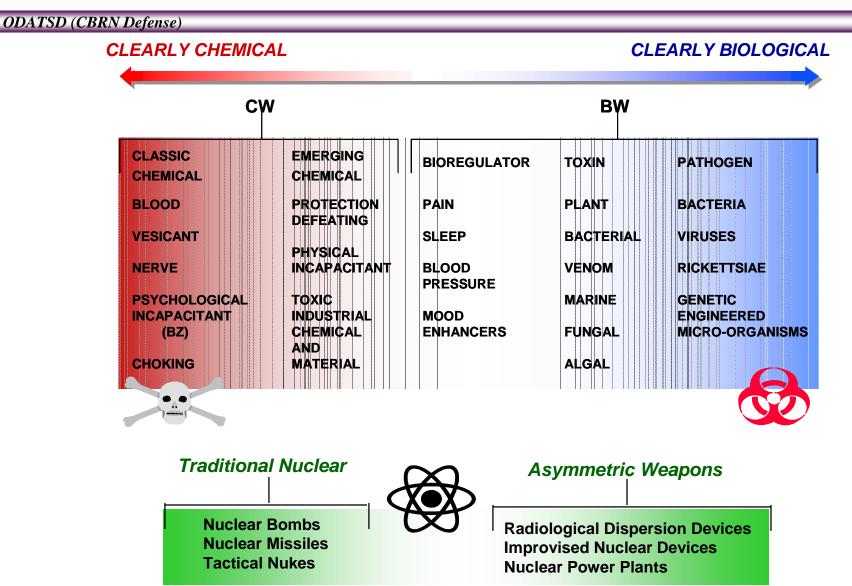


CBRN Defense Program Paradigm Shift

- Prior to the transformation, the major focus to provide improved capabilities for the warfighter to survive, fight, and win on any battlefield contaminated with chemical and biological weapons.
- The current paradigm shift directs both a broadening and deepening of the CBRNDP.
 - ✓ CBRN consequence management (about 1997)
 - ✓ Force protection (in 1999)
 - ✓ Homeland Defense (in 2002)
 - ✓ Visibility of "radiological and nuclear" aspects of the program (2003)
 - ✓ Inclusion of the US Coast Guard (2004)
- This broadening requires a carefully developed program strategy to ensure that warfighter capabilities are maintained and advanced concurrently with these added missions.

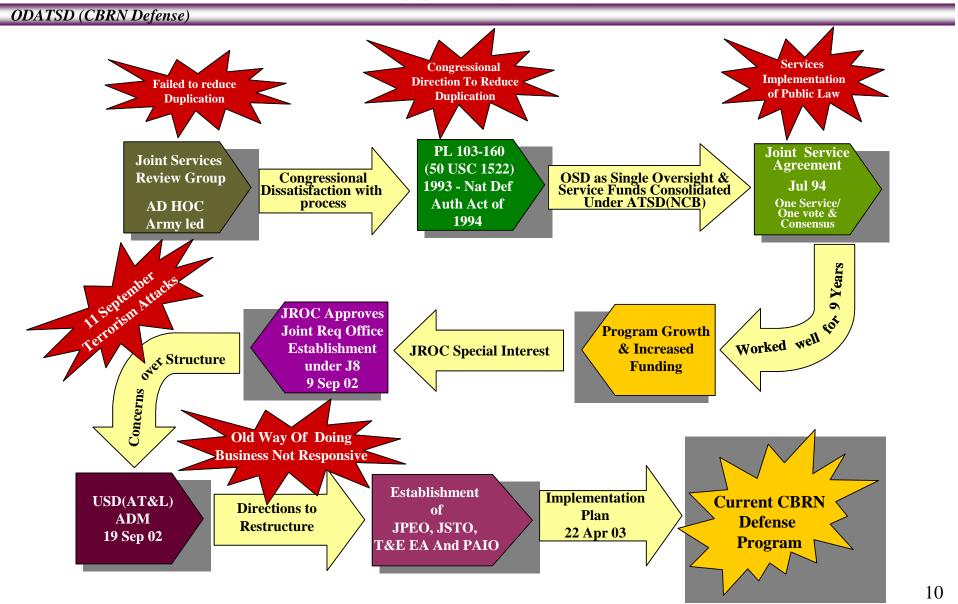


CB Agent Threat Spectrum





Joint CBRN Defense Program Restructure



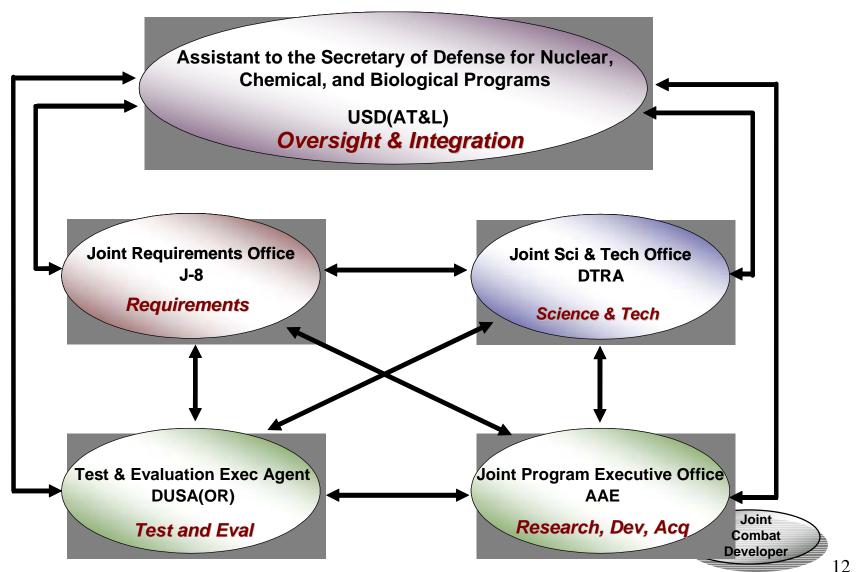


Establishment of Three New Organizations

Joint Service	ce Agreement	CBRNDP Restructure		
Organization	Responsible Agency	Organization	Responsible Agency	
Joint Service Integration Group (JSIG)	Training and Doctrine Command	Joint Requirements Office (JRO)	J-8 Joint Staff	
Joint Service Material Group (JSMG)	Army Material Command	Joint Science and Technology Office (JSTO)	Defense Threat Reduction Agency	
		Joint Program Executive Office (JPEO)	Army Acquisition Executive	



CBRN Defense Program Interface





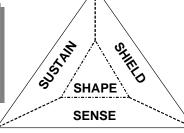
Joint Functional Concept and Joint Core Capabilities Summary

ODATSD (CBRN Defense)

Joint Functional Concept

➤ SENSE – The capability to continually provide the information about the CBRN situation at a time and place by detecting, identifying, and quantifying CBRN hazards.

> SHIELD - The capability to shield the force from harm caused by CBRN hazards.



SUSTAIN – Enables the quick restoration of combat power.

SHAPE - Provides the ability to characterize the CBRN hazard to the force commander - visualize the sequence of events that moves the force from its current state to those end states.





Joint Core Capabilities Summary

SENSE

Point Detection
Stand-off Detection

NBC Reconnaissance

(Chemical, Biological, & Radiological, Nuclear)

SHIELD

Respiratory and Ocular Protection Percutaneous Protection Expeditionary Collective Protection Medical Prophylaxes

SHAPE

Integrated Early Warning
Battle-space Management
Battle-space Analysis

<u>SUSTAIN</u>

Individual Decon
Equipment Decon
Fixed Site Decon
Medical Diagnostics
Medical Therapeutics



Results of Restructure

- Requirements Efforts Elevated to Joint Staff Level
- Focused S&T in a Single Organization
- Joint Service PEO Established
 - Reduction Of Milestone Decision Authorities from 9 to 2
 - Milestone Decision Authority for High Interest/High Value Programs At AT&L Level (Sentinel Programs)
- Single Joint Service Test Organization Designated



Program Corporate Goals



CBRN Defense Program Corporate Goals

ODATSD (CBRN Defense)

Goal 1

Develop *new or improved* CBRN defense capabilities to meet Joint Acquisition Objectives at reduced costs and on schedule

Goal 2

Develop and support a *Science and Technology Base Program* that ensures technological superiority, avoids technological surprises, and integrates the DoD and other Federal agency CBRND research efforts

Goal 3

Develop and support DoD standardized, tested, and accredited CBRN defense *Modeling and Simulation (M&S) capabilities* to meet DoD analysis, acquisition, and training M&S requirements at all levels



CBRN Defense Program Corporate Goals (Con't)

ODATSD (CBRN Defense)

Goal 4

Develop and support *improved CBRNDP test and evaluation processes* and capabilities to ensure that sufficient data are obtained to support materiel characterization, systems of systems integration, and information flow in a timely and cost effective manner

Goal 5

Leverage DOD CBRN defense expertise to support vital national programs

Goal 6

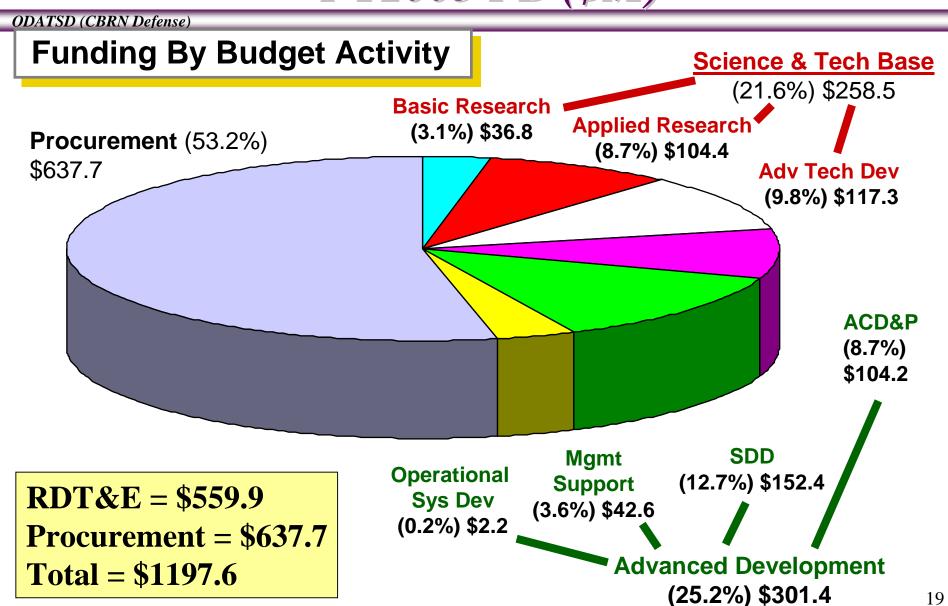
Improve DOD CBRN defense management practices-become a high performance organization



FY05 President's Budget Submission

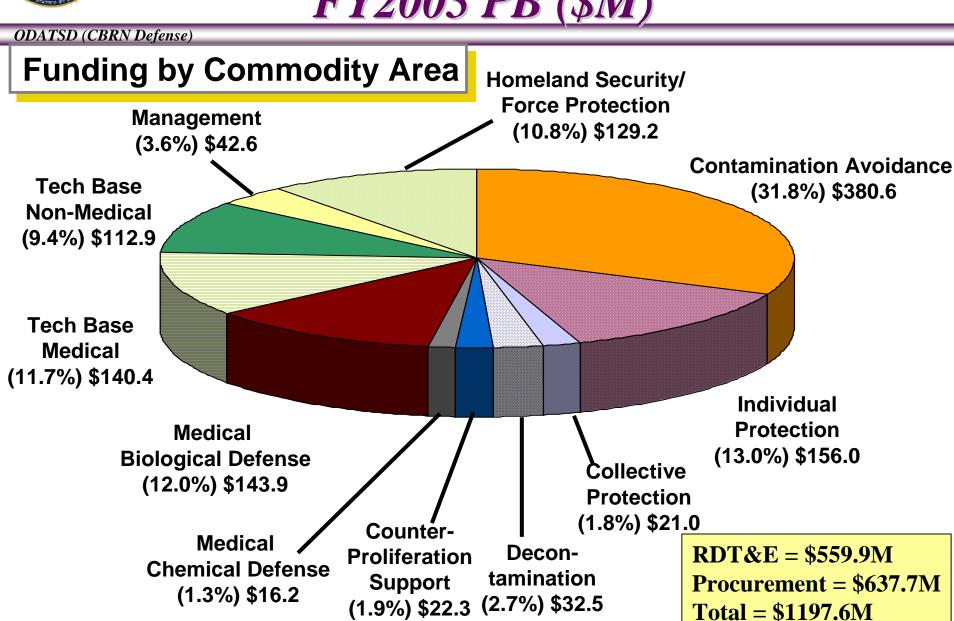


DoD CBRN Defense Program FY2005 PB (\$M)





DoD CBRN Defense Program FY2005 PB (\$M)





FY 04 CB Defense Program Initiatives Fund



CB Defense Program \$25M Initiatives Fund

ODATSD (CBRN Defense)

<u>FY03:</u>

Established for <u>6.2</u> Applied Research



FY04:

Established for <u>6.3</u>
Advanced Technology
Development

Directed to be allocated by the Secretary of Defense "among the program proposals listed..."



Directed to be allocated among "programs which yield the greatest gain in our chem-bio defensive posture,"

New strategy in FY04 needed to ensure a full and open competition through the use of competitive procedures



CB Defense Program Initiatives Funds Methodology

ODATSD (CBRN Defense)

Broad Agency Announcement

- Satisfies the intent of Congress
- Provides for broad solicitation of proposals
- Facilitates open competition
- Most compatible with Scientific Research and Experimentation
- Mechanism widely used for research contracts (NSF, NIH; recommended by NAS – Institute of Medicine)
- Allows selection of technologies with maximum potential for meeting the needs of the DoD



CB Defense Program Initiatives Fund Milestones

> Feb 24	BAA Draft completed and submitted for approval
> Apr 9	BAA presolicitation notice
> Apr 23	BAA announced and opens
May 24	BAA closes and review processes begin
May 24 – June 30	Scientific & Programmatic Reviews
➤ Jul 15	Allocation decision and notification
➢ Sep 30	Contract Awards



Initiative Fund Review Process

ODATSD (CBRN Defense)

Approval

ATSD (NCB)



Deputy Assistant to the Secretary of Defense for Chemical/Biological Defense (DATSD(CBD))

Tier 2 Programmatic Review



Joint Integration Panel (JIP)

Executive Committee: DATSD(CBD), chair; JSTO(CB); JRO(CBRN); JPEO(CBD)



Tier 1 Scientific Peer Review **Peer Review Panels (PRPs)**

Core Directorate: JSTO(CB)

Panel Chairs: Capability Area Program Officers

Panel Members: Scientific experts in capability areas

2-tiered process modeled after a study by the National Academy of Sciences Institute of Medicine that garnered high praise from the scientific community, advocacy groups, and Congress.



Other Initiatives

ODATSD (CBRN Defense)

International Programs

Institute of Medicine/National Research Council Study

Project BioShield

Biological Agent Security (Biosurety)



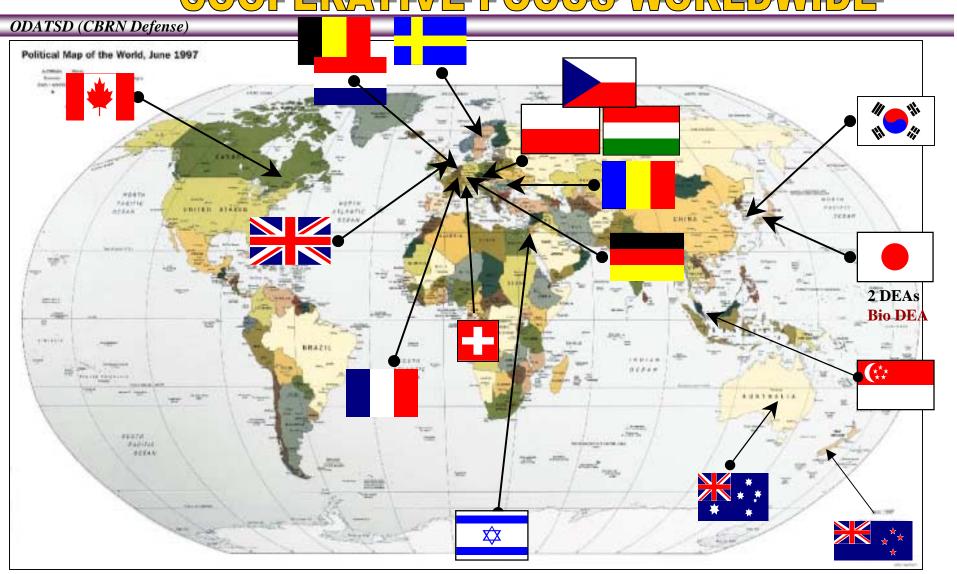
International Partnership





CB DEFENSE

COOPERATIVE FOCUS WORLDWIDE





Research and Development Agreements In Place







Smallpox Vaccine Development (Canada)



- CB Suit Technologies (Singapore)
- CB Agent Water Monitor (Singapore)



Collective Protection (United Kingdom)



Plague Vaccine Development (United Kingdom, Canada)



Fox Logistics



CBR MOU





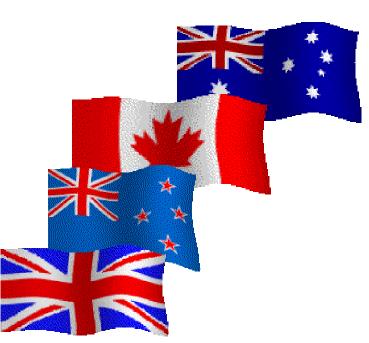
- Trinational MOU Among US, Canada, United Kingdom
- Established in 1980, Updated MOU, Includes New Capability,
 Signed 1 June 2000
- Makes Rational Use of US/UK/CA Resources in CBD Defense
- Addresses Critical Issues in
 - Requirements for CBD Materiel
 - Doctrine Related to the Employment of CBD Materiel
 - Cooperative Development of CBD Materiel
 - Joint Acquisition of CBD Materiel



The Technical Cooperation Program



- Established in 1948, Brings
 Together Defense Related
 Research in U.S./UK/CA/AS/(NZ)
- Chemical, Biological and Radiological Defense Group Lead for CBR Defense Research
- Seven Subordinate Groups
 Focusing on All Aspects of CBR
 Defense
 - Medical Countermeasures
 - Biological Detection
 - Toxicology
 - Radiological Defense
 - Individual Protection

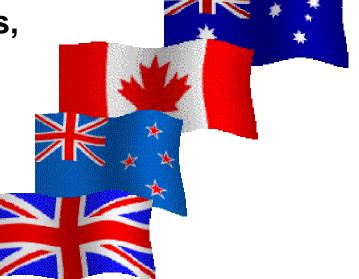




International Standardization

- Standardization of Procedures, Equipment and Doctrine Through Two Mechanisms
 - NATO Land Group 7
 - American British Canadian Australian (ABCA) Armies
- Both Develop Common Practices, Equipment Specifications, Test Protocols, etc, through the Establishment of Standard Agreements:
 - STANAGS (NATO)
 - QSTAGS (ABCA)







Institute of Medicine/National Research Council Study on Medical BW Agent Countermeasures



IOM Study Summary

- DOD has fielded ONE licensed medical countermeasure since the Desert Storm
- DOD efforts are "fragmented of responsibility and authority, changing strategies, and lack of financial commitment"
- DOD has only \$267 M (annual) budget for CBD; compare with NIH \$1.7 B (annual); or Project BioShield \$5.6 B (10 years)
- Other concerns: Limited facilities, personnel expertise and retention, shortage of non-human primates and testing facilities



IOM Recommendations

- Integrate all Bio Defense Activities
- Create DOD Medical Biodefense Agency
- Establish External Review Committee
- Organize with knowledgeable staff
- Increase funding \$100M to \$300M+ over next five years
- Partner with industry, academia, NIH
- Implement the FDA "Animal Rule"
- Establish streamlined FDA sensitive RD&A
- Increase support for bottlenecks: Infrastructure and primate capability



Ongoing DOD Actions

- Analyze results of the IOM study
- Provide recommendations to AT&L/ DepSecDef
- Develop recommended Course of Action and present best options to U.S. Congress
- Continue to make use of the 2002 FDA "Animal Rule" as a viable pathway to CBD medical product approval
- Develop interagency agreements to leverage partnerships with DHHS, DHS, and industry, for example Project BioShield



Project BioShield



Project BioShield

ODATSD (CBRN Defense)

Presidential initiative designed to

attract industry interest to develop

and manufacture needed medical

countermeasures against weapons of

mass destruction.



Project BioShield: Highlights

- Appropriation of \$5.6 billion / 10 years DHHS/DHS
- ➤ The legislation has three distinct features:
 - Provides accelerated funding for research and development
 - ✓ Allows contracts to procure promising medical countermeasures still undergoing clinical testing
 - ✓ Provides for the emergency use of countermeasures not yet approved by the Food and Drug Administration
- First procurements for FY04 include anthrax, botulism and smallpox



Project BioShield: Challenges for Industry

- Limited market for CBD products: No commercial market, or "Government-only" market
- Cost of maintaining knowledge and technology base for future production runs to replenish Strategic National Stockpile
- ➤ Intellectual property/ patent concerns
- ➤ Issues of product liability (indemnification or medical product insurance)



DoD's Role in BioShield

ODATSD (CBRN Defense)

- ➤ Leverage military requirements for medical countermeasures with DHS and DHHS resources for research, development and procurement
- ➤ Continue to produce viable medical product candidates from the DoD research tech base
- ➤ Maintain the unique DoD intramural medical biodefense program that includes necessary laboratory expertise and infrastructure

DoD role in Bioshield is significant and this legislation has the potential to streamline the acquisition of needed WMD medical countermeasures for the government.



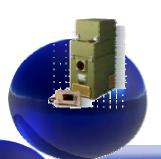
Delivering New Capabilities to the Warfighter



Accelerating Technology Transition Operation Iraqi Freedom

ODATSD (CBRN Defense)

Fox TICs Data Chip



LANGE OF

Chemical Biological Protective Shelter CBPS



Special Purpose Automatic Chemical Agent Alarm (ACADA)

Navy Bio Detector



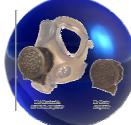


Decontamination System (Karcher)





1600+ Special Fit Protective Suits



M40 Mask Voicemitter



Dry Filter Unit 2000 (DFU)



Chemically Protected
Deployable Medical System
(CP DEPMEDS)



Reactive Skin
Decontamination Lotion
(RSDL)



Antidote Treatment, Nerve Agent Autoinjector (ATNAA)



Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA)

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www.fedbizopps.gov www.acq.osd.mil/cp/