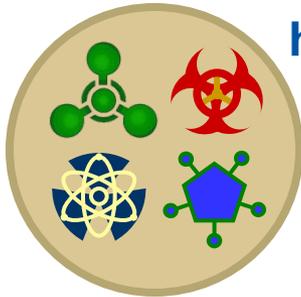




The Challenge

**Define, Design, Develop, Deliver and Dispense
Medical Countermeasures to reduce the adverse
health consequences of public health emergencies**



**Address a diverse
set of threats:
CBRN, Influenza & EIDs**



**Consider the needs of a
large, diverse population**



**Engage industry & address product
development challenges:
lengthy, risky, and expensive**



**Establish & Prioritize MCM
requirements and research,
development, and acquisition programs**



**Establish positioning,
deployment and use
strategies for medical
countermeasures**





The Interagency Framework and Initiatives



Guiding Policies and Statutes:

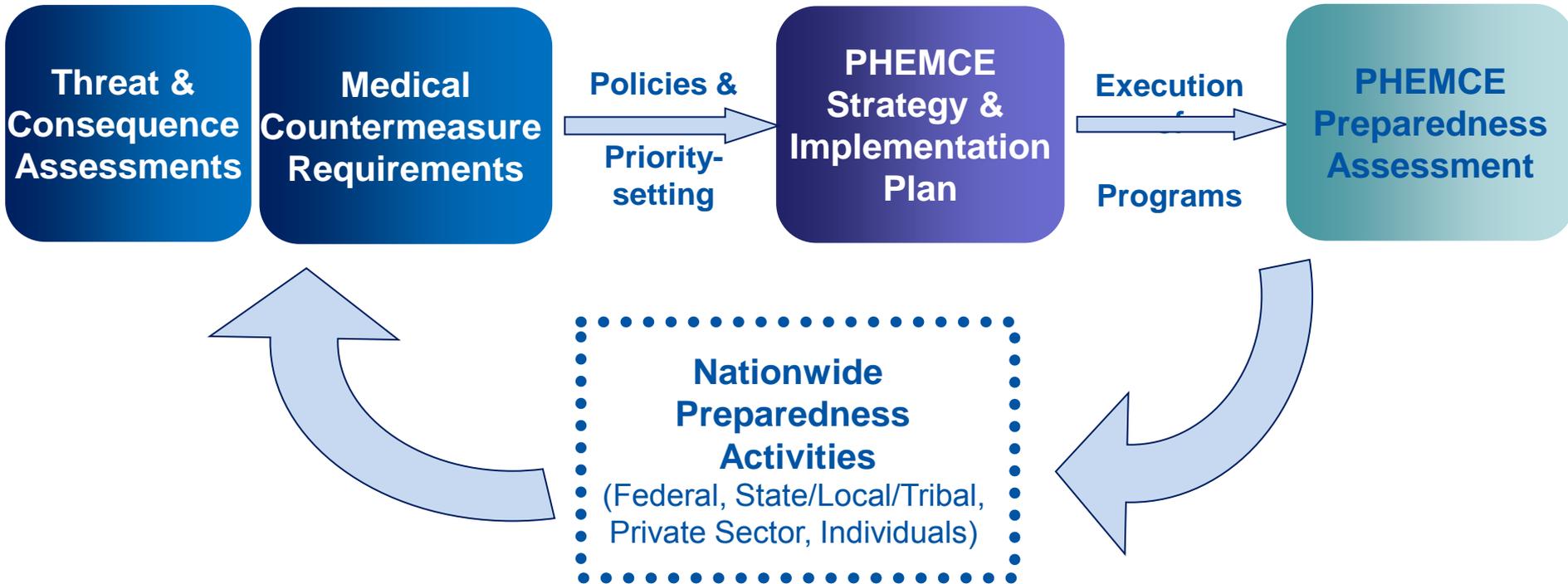
Public Health Security and Bioterrorism Preparedness & Response Act of 2002

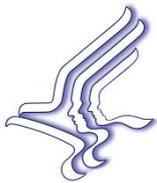
Project BioShield Act of 2004, National Strategy for Pandemic Influenza (2005)

Pandemic and All-Hazards Preparedness Act of 2006

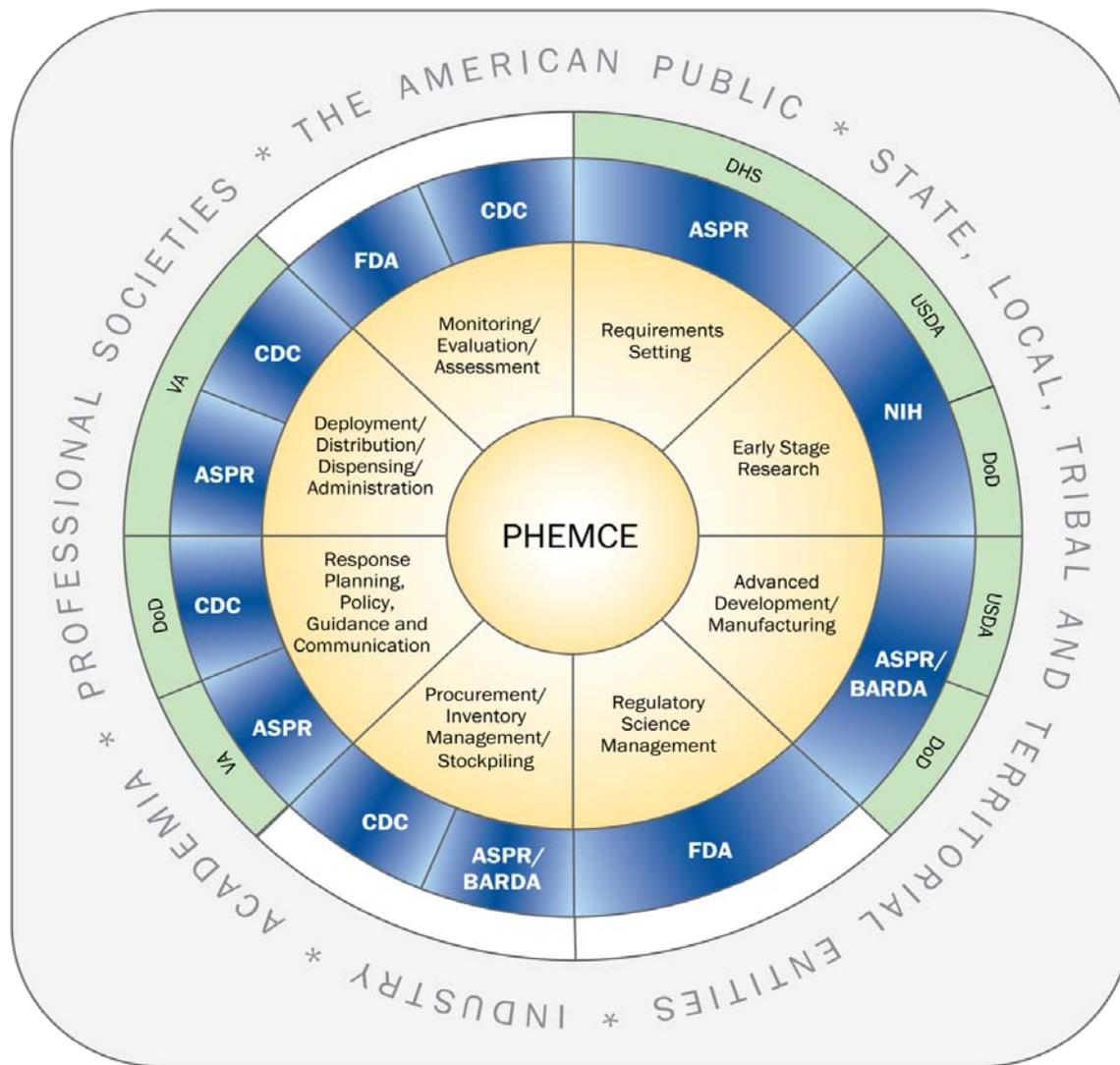
National Health Security Strategy (2009), PPD-8, EO 13527

HSPD-10, HSPD-18, HSPD-21 and HSPD-22





PHEMCE Partner Lead Roles



Key

- PHEMCE Mission Components
- HHS PHEMCE Agencies
- Non-HHS PHEMCE Agencies
- Non-Federal Stakeholders



Interagency Guidance:

The 2012 PHEMCE Strategy and Implementation Plan

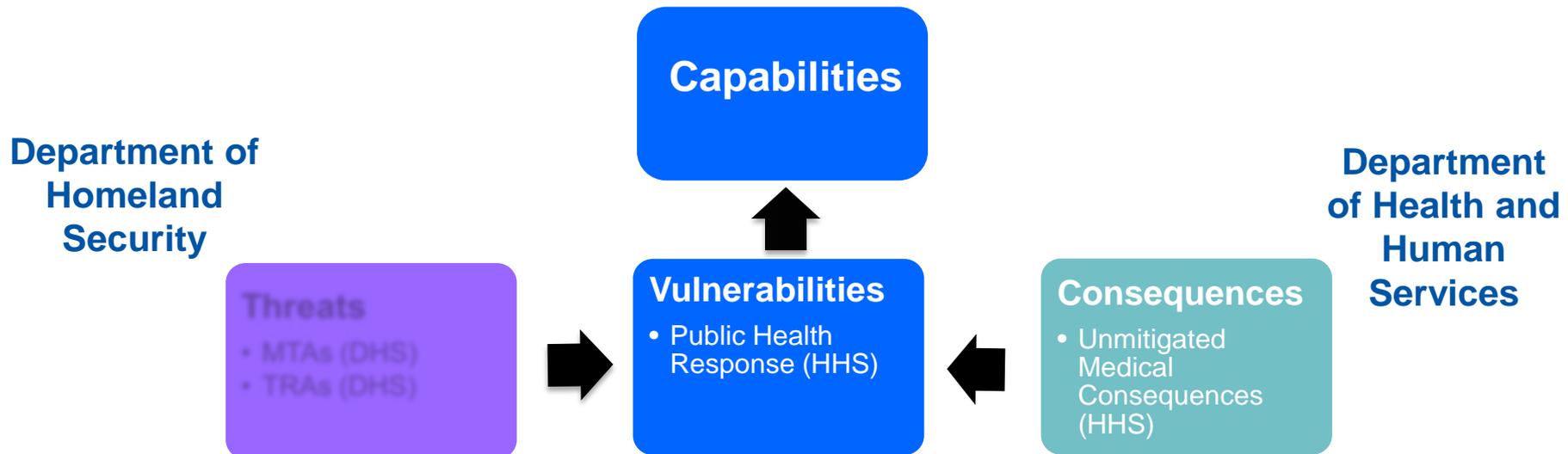
- **The Strategy Document articulates the strategic direction and guides policies and decisions for PHEMCE end-to-end mission**
- **2012 SIP: Updates strategy developed in 2007**
 - CBRN threats, influenza and emerging infectious diseases
 - End-to-end mission space addressed
 - Requirements
 - Early-stage R&D
 - Advanced development
 - Regulatory science
 - Acquisition
 - Inventory management
 - Response planning
 - Utilization
 - Post-event monitoring
- **Objectives address requirements setting:**
 - Medical consequence modeling
 - Public health response modeling
 - End User needs
- **PHEMCE Strategy is released, Implementation Plan due in Oct 2012**



Development of an Integrated Analysis Process



- **The threat**
 - Scientific and medical characteristics of the threat agent and resultant disease
 - Medical consequence modeling
 - **Material Threat Assessments (MTAs) and Material Threat Determinations (MTDs)**
- **The target population**
- **Estimated requirements**
- **Deployment and utilization planning (Concept of Operations)**





Integrated MCM Requirements Process



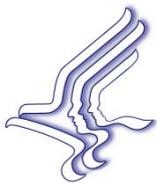
- **Lead development of a *capabilities-based* analytic approach to improve preparedness and response for HHS**
 - Quality assessment
 - Quality improvement
- **Lead HHS efforts in the development of an *integrated medical countermeasure analysis process***
 - In partnership with DHS and others to support public health emergency preparedness decision making
- **Factors Considered:**
 - The threat
 - The target population
 - Available next-generation countermeasures
 - Product specifications
 - Deployment and utilization planning (CONOPs)
 - Estimated requirements



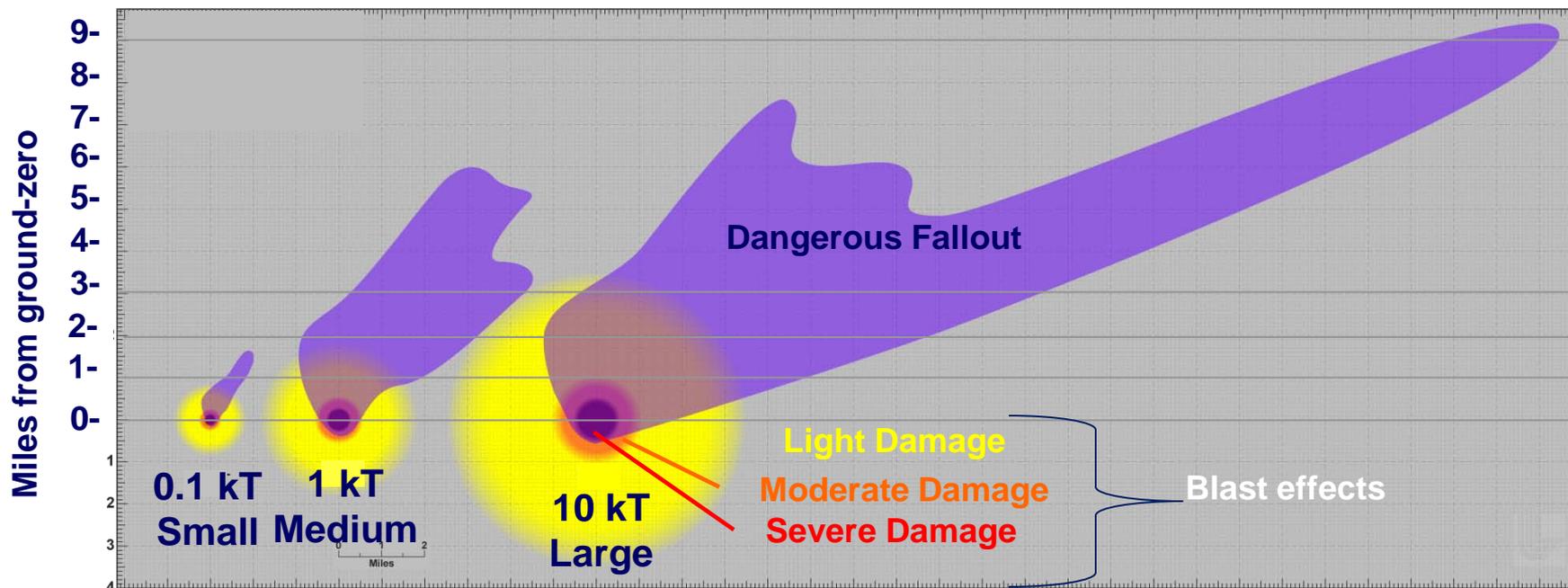
MCM Requirements Addresses of Number of Issues



- ***MCM Type:*** What type(s) of medical countermeasures (e.g., vaccines, drugs for prophylaxis, drugs for treatment, diagnostics) could mitigate adverse health effects?
- ***MCM Scale:*** How many medical countermeasures are needed?
- ***MCM Characteristics:*** What product-specific characteristics would facilitate an effective public health and medical response to a mass-casualty **incident**?
- ***MCM Use in an Event:*** How will MCMs be used given existing or proposed incident CONOPS?



Nuclear Detonation: A CBRN Medical Emergency





Current NucRad Requirements Activities



- **Scenario Based Analysis**
 - Improvised nuclear device (IND) detonation
 - Radiological dispersal device / (radiocesium PSR amendment)
- **Product Specific Requirements**
 - Gastrointestinal-ARS
 - Pulmonary radiation injury
 - Antimicrobial prophylaxis and treatment
 - Potassium iodide (completed August 2012)
- **SNS Stockpile Assessments**
 - IV fluid formulary review
 - Burn and blast kit formulary review



Recent Tactical Initiatives

- **IV Fluids assessment of SNS Supply**
 - **Impact:** Updating current formulations in SNS to recommend potential procurement strategies
- **Burn Blast Kit Assessment**
 - **Impact:** Assessment of kits in SNS and determination of current practices or new direction
- **Ondansetron Formulary Determination**
 - **Impact:** Updating formulary for MCM to acquire SNS to replace other products less suited as anti-emetics for radiation treatment
- **Radiation Emergency Medical Management**
 - **Impact:** www.remm.nlm.gov focuses on how to diagnose and treat radiation exposure
- **Chemical Hazards Emergency Medical Management**
 - **Impact:** <http://chemm.nlm.nih.gov> focuses on how to diagnose and treat chemical exposure