



*United States Department of*

**Health & Human Services**

**Office of the Assistant Secretary for Preparedness and Response**



# **2012 HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan**

*Carol D. Linden, Ph.D.  
Principal Deputy Director  
BARDA*

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# Overview of 2012 PHEMCE Strategy and Implementation Plan



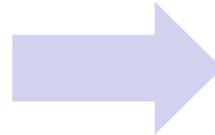
- *PHEMCE Strategy and Implementation Plan (SIP)* will set the course for all PHEMCE activities for next five years
- Updates 2007 SIP, which established PHEMCE priorities with focus on advanced research and development
- *Strategy* – Mission, scope, goals, and objectives
  - Released in June 2012
  - <http://www.phe.gov/phemce/strategy>
- *Implementation Plan* – Prioritized programs to accomplish goals and objectives identified in Strategy
  - Target public release early Nov 2012



# Scope

## 2007 SIP

- Focused primarily on advanced research and development
  - Spend plan for BioShield Special Reserve Fund
- Focused on CBRN threats

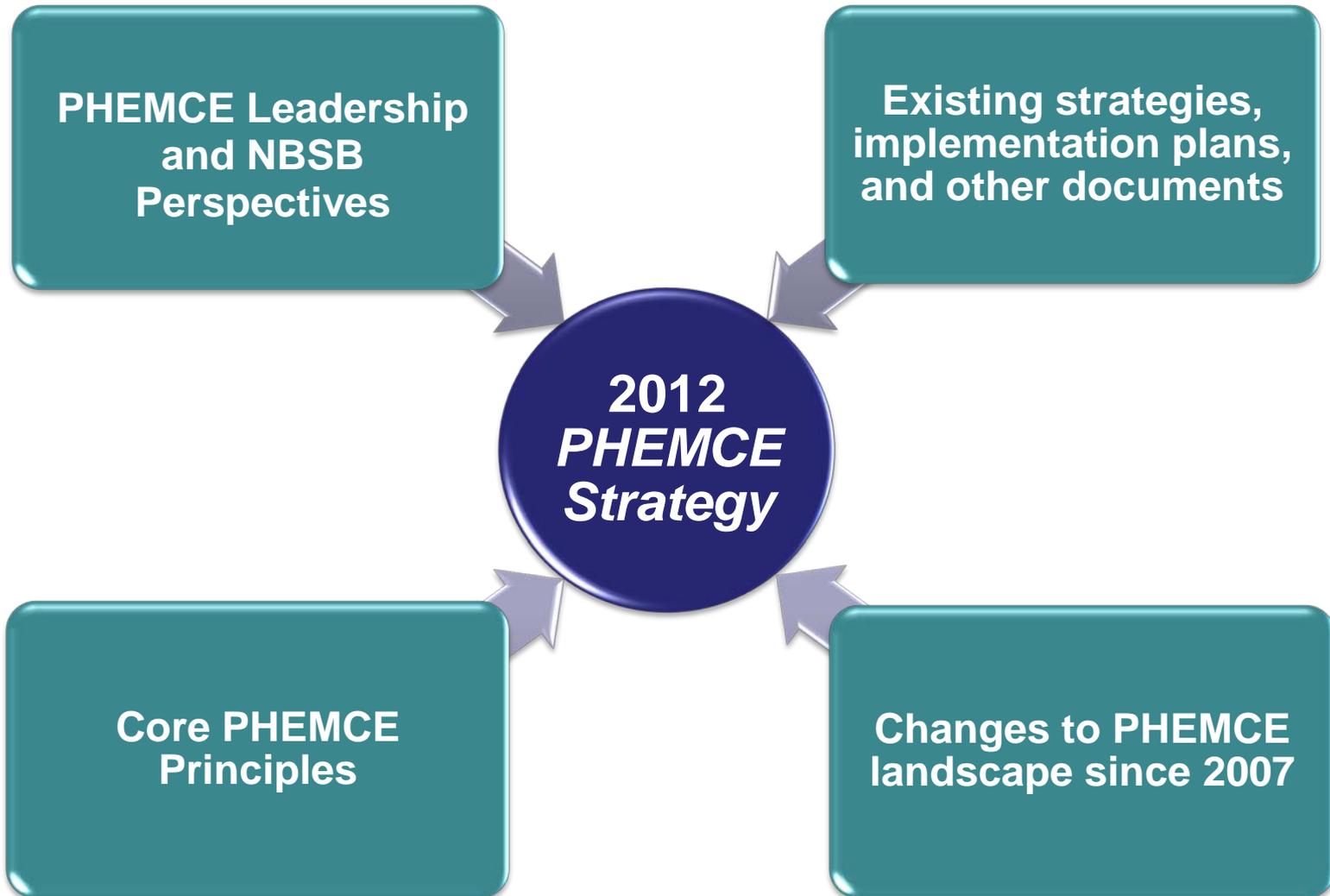


## 2012 SIP

- Focuses on all aspects of PHEMCE mission space
  - Spans requirements through utilization
  - Include SRF priorities
- CBRN as well as pandemic influenza and emerging infectious diseases



# Key Inputs to 2012 PHEMCE SIP



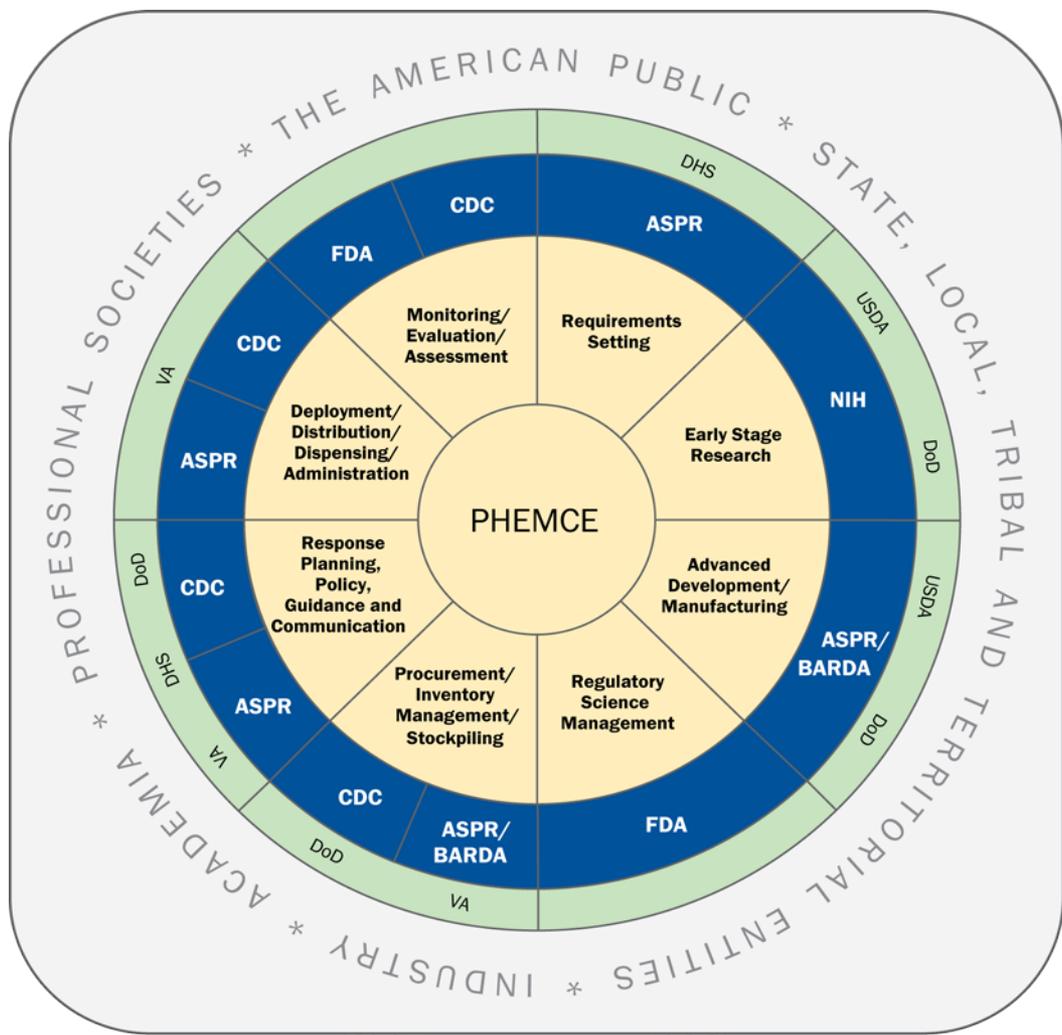


# Related Strategic Plans/Documents



- 2010 The Public Health Emergency Medical Countermeasures Enterprise Review
- 2011 BARDA Strategic Plan
- 2009 National Health Security Strategy & Biennial Implementation Plan
- 2011 ASPR Strategic Plan & 2012 Implementation Plan
- 2010 National Biodefense Science Board (NBSB) Report: Where are the Countermeasures? Protecting America's Health from CBRN Threats
- 2011 Advancing Regulatory Science at FDA: A Strategic Plan
- 2011 (Draft) CDC/OPHPR Strategic Plan
- 2010 National Vaccine Plan
- 2005 National Strategy for Pandemic Influenza & HHS Implementation Plan (2006)
- 2007 HHS Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats
- 2011 (Draft) National Preparedness Goal

# PHEMCE Lead Roles



### Key

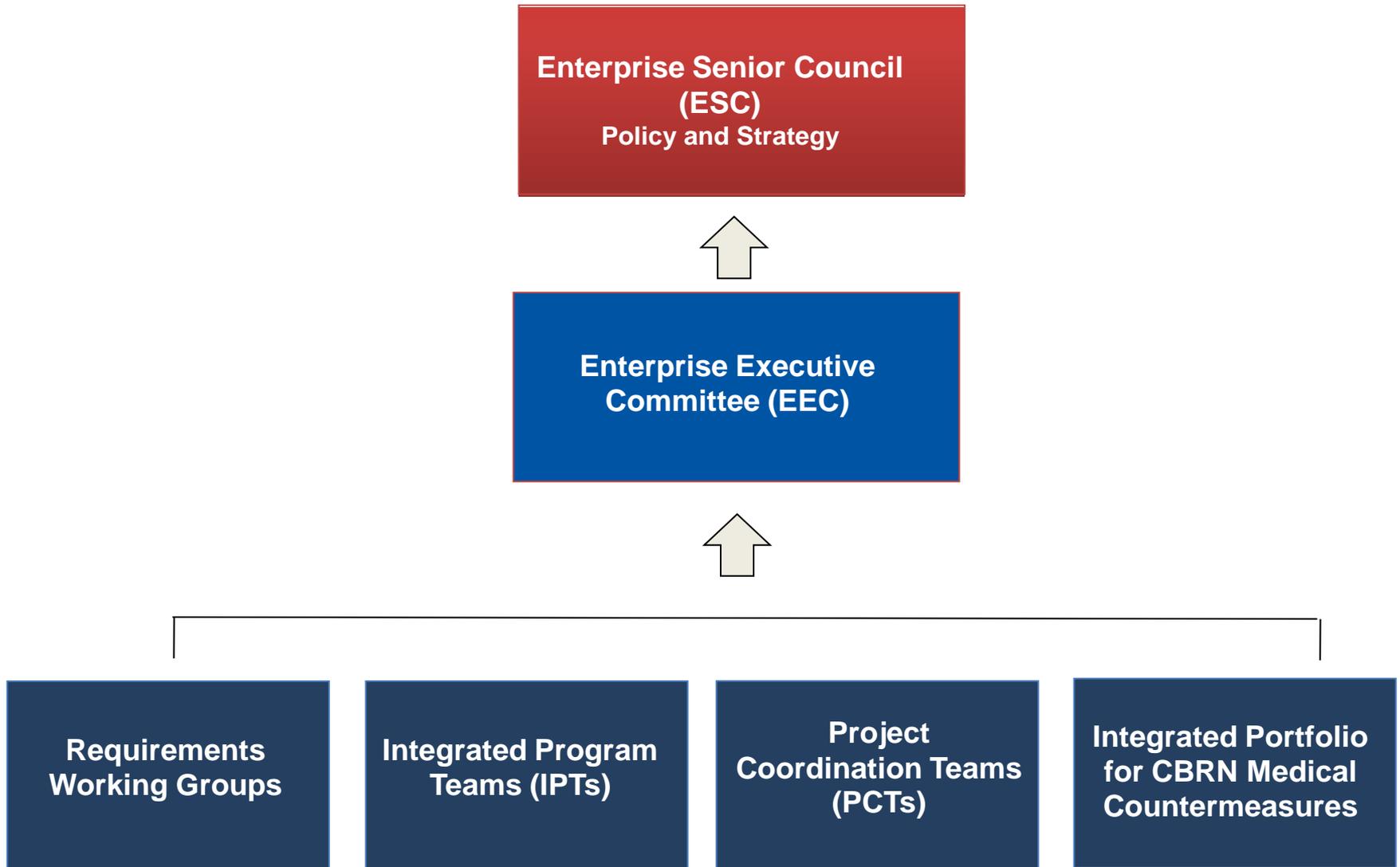
- PHEMCE Mission Components
- HHS PHEMCE Agencies
- Non-HHS PHEMCE Agencies
- Non-Federal Stakeholders

### Acronyms

- PHEMCE:** Public Health Emergency Medical Countermeasure Enterprise
- DHS:** Department of Homeland Security
- DoD:** Department of Defense
- USDA:** U.S. Department of Agriculture
- VA:** Department of Veterans' Affairs
- HHS:** Department of Health and Human Services
- 
- ASPR:** Assistant Secretary for Preparedness and Response
- BARDA:** Biomedical Advanced Research & Development Authority
- CDC:** Centers for Disease Control and Prevention
- FDA:** Food and Drug Administration
- NIH:** National Institutes of Health



# PHEMCE Governance Structure





# Prioritization Framework



- **Goal:**

- An integrated prioritization framework for PHEMCE investments based on common vision across PHEMCE mission components

- **Core Principles**

- Limit adverse health impact
- Stewardship of resources that create an enduring capability

- **Essential Criteria (in rank order)**

1. Threat
2. Multi-functionality
3. Operational capacity



# 2012 PHEMCE Strategic Goals



## Goal 1

- Identify, create, develop, manufacture and procure critical medical countermeasures

## Goal 2

- Establish and communicate clear pathways to facilitate medical countermeasure development and use

## Goal 3

- Develop logistics and operational plans for optimized use of medical countermeasures at all levels of response

## Goal 4

- Address medical countermeasure gaps for all sectors of the American civilian population



# Goal 1: Identify, create, develop, manufacture and procure critical MCMs.



- ***Objective 1.1 Develop a strategic framework to prioritize PHEMCE resources and investments.***
- Two Core Principles
  - Limit adverse health impact
  - Effective stewardship of resources that create an enduring capability
- Three Primary Criteria: threat, multi-functionality, operational capacity
- Three Moderating Criteria: at-risk population needs, cost, time
- Evolving application of prioritization framework over next two years
  - Strategic end-states
  - Portfolio Reviews
  - Multi-year budgeting
  - Portfolio Management
  - Decision-support methods (e.g. SNS RPI)



# Goal 1: Identify, create, develop, manufacture and procure critical MCMs.



- **Objective 1.2** *Utilize consistent approaches for medical consequence and public health response assessments and medical countermeasure requirement setting that include consideration of effective production, storage, deployment, and administration strategies.*
  - **Action:** Enhance the development of clear and rigorous civilian medical countermeasure (MCM) requirements, including capabilities-based requirements



# Goal 1: Identify, create, develop, manufacture and procure critical MCMs.



- **Objective 1.3** *Ensure a robust and sustainable product pipeline for medical countermeasures that emphasizes multi-functional capabilities (e.g., platform technologies, host-based innovations, broad-spectrum medical countermeasures) rather than stand alone outcomes and includes consideration of viable commercial markets and/or routine public health applicability.*
  - **Action:** Invest in research, advanced development and acquisition of current and novel products following the prioritization framework



# Goal 1: Identify, create, develop, manufacture and procure critical MCMs.



- ***Objective 1.4 Promote effective domestic and international partnerships with developers and manufacturers and support core services.***
  - **Action:** Maintain a wide array of product development and support service contracts to provide infrastructure capabilities for MCM development
  - **Action:** Enter into strategic bilateral and multilateral engagements with international partners to identify joint opportunities for product development



## GOAL 2. Establish and communicate clear pathways to facilitate MCM development and use.



- ***Objective 2.1 Identify scientific and regulatory issues that challenge medical countermeasure development or use during public health emergencies and coordinate activities among PHEMCE partners to address those challenges.***
  - **Action:** Identify and resolve the regulatory and scientific challenges that impede MCM development and use.
  - **Action:** Build the science base necessary to support MCM development and regulatory assessment
  - **Action:** Assess the legal, regulatory, and policy environments regarding MCM development, distribution, administration, and use and propose new approaches where necessary



## GOAL 2. Establish and communicate clear pathways to facilitate MCM development and use.



- **Objective 2.2** *Assist medical countermeasure developers in working interactively with FDA during product development and regulatory review*
  - **Action:** Clarify regulatory pathways and reduce regulatory barriers
  - **Action:** Provide product development core services to MCM developers and manufacturers



## GOAL 3. Develop logistics and operational plans for optimized use of MCMs at all levels of response.



- ***Objective 3.1 Promote innovative approaches to inventory management to enable a sustainable preparedness infrastructure***
  - **Action:** Optimize the Strategic National Stockpile (SNS) formulary
  - **Action:** Cost-effectively manage SNS assets
  - **Action:** Enhance the long-term sustainability of the SNS



## GOAL 3. Develop logistics and operational plans for optimized use of MCMs at all levels of response.



- **Objective 3.2** *Develop and communicate medical countermeasure utilization policy, guidance and response strategies, including FDA regulatory frameworks, that are responsive to end-user needs and that are integrated with SLTT and private sector response plans, and when possible international partners, and that ensure timely, safe, and effective medical countermeasure distribution and utilization.*
  - **Action:** Strengthen the feedback loop between the end-users and developers of MCMs
  - **Action:** Enhance federal response plans
  - **Action:** Ensure preparedness in key federal policy and response capabilities
  - **Action:** Support state, local, tribal and territorial response efforts
  - **Action:** Identify and address barriers to building a sustainable MCM global infrastructure



## GOAL 3. Develop logistics and operational plans for optimized use of MCMs at all levels of response.



- **Objective 3.3** *Develop and provide medical countermeasure communications, training, and education information to inform all stakeholders.*
  - **Action:** Develop a comprehensive communications program and multi-year implementation plan
  - **Action:** Test the effectiveness of MCM-related public health communication materials
  - **Action:** Develop and implement a plan to disseminate best practices for establishing and maintaining regional coordination for public health emergencies



## GOAL 3. Develop logistics and operational plans for optimized use of MCMs at all levels of response.



- **Objective 3.4** *Develop and implement strategies to assess, evaluate, and monitor medical countermeasure safety, performance, and patient compliance during and after a public health emergency response.*
  - **Action:** Develop an Action Plan that will serve as the overall PHEMCE plan for monitoring the safety and performance of medical countermeasures during public health emergencies



## GOAL 4. Address MCM gaps for all sectors of the American civilian population.



- **Objective 4.1** *Develop medical consequence and public health response assessments and requirements setting for at-risk individuals.*
  - **Action:** Consider at-risk population needs in every stage of the MCM requirements-setting process
  - **Action:** Support research to close important knowledge gaps regarding susceptibility differences and/or altered disease severity in at-risk populations
  - **Action:** Incorporate subject matter expertise to inform the development of both MCM requirements and strategies to assure availability of these MCMs for at-risk populations



## GOAL 4. Address MCM gaps for all sectors of the American civilian population.



- ***Objective 4.2 Support medical countermeasure advanced development and procurement for at-risk individuals.***
  - **Action:** Include consideration of at-risk population needs in SNS formulary analyses
  - **Action:** Support expanding MCM label indications to at-risk populations during the development of priority MCMs



## GOAL 4. Address MCM gaps for all sectors of the American civilian population.



- **Objective 4.3 Develop and implement strategies, policies, and guidance to support the appropriate use of medical countermeasures in all civilian populations during an emergency.**
  - **Action:** Address regulatory challenges associated with use of products intended for at-risk populations
  - **Action:** Ensure that public health and medical information is delivered in a manner that takes into account the range of communication and other functional needs of the intended recipients, including at-risk individuals
  - **Action:** Identify and comprehensively integrate departmental activities related to the needs of children
  - **Action:** Anticipate and pro-actively address the needs of at-risk populations during a disaster



# Sections in Implementation Plan



- **Threat-Based Approaches**
  - While the PHEMCE is evolving towards capability-based approaches, we will maintain key threat-based approaches needed to address these dangers to national health security
- **Capabilities-based approaches**
  - The PHEMCE is evolving from programs focused on rapidly acquiring needed initial medical products to bolster preparedness, to programs that will provide more flexible and sustaining capabilities over the long term.



# Next Steps



- Public release of Implementation Plan November 2012
- Monitor and track implementation (Nov – 5 years)
  - ASPR will institute a PHEMCE-wide tracking mechanism and report progress against these activities regularly