Existing Federal Guidance on INDs and Challenges to Operations in Communities Outside Detonation Site

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ASPR’s Role

• We plan for all hazards
• We augment State and Local capabilities when they are requested
• We are the coordination point for all civilian federal medical and public health response
Events come in all shapes and sizes

- 9/11 and Anthrax
- Katrina, Rita, Wilma
- Re-emerging H5N1
- H1N1 Pandemic
- Ike, Gustav
- Japan Earthquake Nuclear Event
- Deepwater Horizon
- Haiti earthquake
- 2011 Tornadoes
- Irene
- Sandy
- 2011
- 2012
Nuclear Detonation: A CBRN Medical Emergency

The Biggest Variable: Scale

Medical Casualties
- Radiation
- Trauma
- Burns
- Psychological

Infrastructure Damage
- Facilities
- Personnel
- Transportation
- Supply

Societal Damage
- Community
- Government

National Planning Translates into Local Efforts

• National Preparedness Goals, September, 2011
• National Response Framework, January, 2008
• National Disaster Recovery Framework, September, 2011
• National Health Security Strategy, 2010
• Homeland Security Presidential Directive
  — National Incident Management System
• Public Health Preparedness Capabilities, March 2011
  — National Standards for State and Local Planning
• National Guidance for Healthcare System Preparedness, January 2012
• Public Health Emergency Medical Countermeasure Enterprise Strategy and Implementation Plan, December 2012
The Interagency Framework

Guiding Policies and Statutes

Threat & Consequence Assessments
Medical Countermeasure Requirements

Policies & Priority-setting

Enterprise* Strategy & Implementation Plan

Program Execution

Enterprise* Preparedness Assessment

Nationwide Preparedness Activities
(Federal, State/Local/Tribal, Private Sector, Individuals)

ASPR’s Role in Federal Capabilities

• Helps Set National Public Health and Health Security Policy
• Sets Requirements for Level of Medical Response Capabilities
• Oversees the Public Health Emergency Medical Countermeasures Enterprise
• Develops New Medical Countermeasures for National Needs
• Oversees HHS Emergency Medical Response Capabilities (e.g. National Disaster Medical Systems)
• Manages HHS Secretary’s Responsibilities for National Disaster Response Plans (ESF #8 – Medical)
• Directs the Hospital Preparedness Program
• Assists in Risk Communication and Public Affairs
• Coordinates Medical and Public Health Responses with other Federal Agencies, State, Local and Tribal jurisdictions
• Coordinates Medical Issues FEMA Regions

ASPR Plans and Responds Across All Hazards
Federal Assets ASPR Helps Deliver:

• Deployable Self-sustained Medical Assets and Personnel
  — Triage, transport, treatment, decontamination
  — Mental Health Teams
  — Public Health Teams
  — Mortuary Teams
• Specific Medical Countermeasures for Rad/Nuc Impacts
  — Hematopoetic, GI, Decorporation, Thermal Burns, Biodosimetry and Diagnostics, Supportive Therapies
• Medical Situational Awareness for National Command
  — HHS Secretary’s Operational Center
• Concepts of Operations Plans and FEMA Regional Coordination
• Supports Input for Disaster Waivers and Legislative Actions
• Supports efforts for Regulatory / Clinical Study Needs
ASPR Organization

Assistant Secretary for Preparedness & Response (ASPR)

Principal Deputy Assistant Secretary for Preparedness & Response (PDASPR)

Chief Operating Officer (COO)

Office of Biomedical Advanced Research & Development Authority (BARDA)

Office of Preparedness & Emergency Operations (OPEO)

Office of Acquisitions Management, Contracts, & Grants (AMCG)

Office of Policy & Planning (OPP)

Office of Financial Planning & Analysis (FPA)

Health Care Operations
Patient Transport
Medical Logistics
CONOPS

Medical Countermeasures
- Biodosimetry & Diagnostics
- Therapeutics
- Manufacturing Coordination

Requirements Setting
Health Security Policy
International Assistance

## National Disaster Medical System At A Glance

### Historical Perspective:
- **Established 1984**
- Collaborative partnership:
  - VA, DoD, HHS, DHS
  - USPHS $\rightarrow$ DHS (‘02) $\rightarrow$ HHS (‘07)
- Authorized by PAHPA 2006
- Three-part mission:
  - Medical response
  - Patient movement
  - Provision of definitive care
- **Nearly 300 missions to date**

### Organization:
- 25 headquarters staff
  - Director and Executive Officer
    - CMO/Operational Medicine Branch
    - Program Development Branch
- Over 7000 intermittent federal employees
- Organized by response teams based on locale and type (example: DMAT CA-1)
- Located across OPEO
  - Patient movement (OPS)
  - Medical response & Def Care (NDMS)

### Operations:
- Primary teams:
  - DMAT: disaster medical care
  - DMORT: disaster mortuary care
  - NVRT: disaster veterinary care
- MSET, IRCT, MAC-ST, JPATS specialty personnel and capability programs
- NDMS is an asset for ESF-8 under ASPR
- Employees provided professional liability, workers comp, USERRA coverage

### Additional Information:
- Evolving capability from “traditional” DMAT 35 to DMAT 50 modular/scalable model
- **Nearly 5000 clinical providers credentialed by NDMS program**
- Most recent missions (2012):
  - Hurricane Sandy (> 7K pt encounters)
  - Sandy Hook mass shooting incident (mental health response with USPHS)
Key Concepts on Patient Surge Using Health Care Coalitions (HCC)

Capturing existing resiliency by changing our viewpoint

How Medical Product Requirements are Shaped

- Scenario Based Analysis – How Much, and What Kind?
  - Improvised nuclear device (IND) detonation
  - Radiological dispersal device / (radiocesium PSR amendment)
  - Level of Public Health Impact (how many injuries, what kind)

- Product-Specific Requirements – Product Characteristics Needed?
  - Gastrointestinal-ARS
  - Pulmonary radiation injury
  - Antimicrobial prophylaxis and treatment
  - Potassium iodide
  - Thermal and Radiological Burns
  - Biodosimetry / Diagnostics

- SNS Stockpile Assessments – Products on Hand and Deliverable?
  - IV fluid formulary review
  - Burn and blast kit formulary review
• Execution of the regulatory path for licensure/approval

• Establishment of a sustainable and affordable preparedness capability (e.g., managed inventory which leverages mainstream clinical use; warm base with surge options, or Vendor Managed Inventory)

• Development of utilization policies and concepts of operation (CONOPS)
Upgrades to Current Capabilities

• 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](http://www.remm.nlm.gov) focuses on how to diagnose and treat radiation exposure
BARDA Has Established Robust CBRN MCM Development Pipeline

• **BARDA CBRN MCM development pipeline has supported 80 candidates since 2004 ($1.6 B)**

• **Biothreats**
  • Anthrax vaccines (7) and antitoxins (7)
  • Smallpox vaccine (3) and antiviral drugs (2)
  • Botulinum antitoxin (1)
  • Other biothreat antimicrobials (4)

• **Rad/Nuc threats**
  • Acute Radiation Syndrome drugs (33)
  • Decomposition agents (6)
  • Thermal burn therapies (2)
  • Biodosimetry devices (11)

• **Chem threats – antidotes & decon (4)**

<table>
<thead>
<tr>
<th>Contractor</th>
<th>Area and Description</th>
<th>Status</th>
<th>Initial/Concurrent Enterprise Support</th>
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</thead>
<tbody>
<tr>
<td>Cellerant</td>
<td>Hematopoietic - cellular therapy: CLT-008/Myeloid Progenitor Cells</td>
<td>Active</td>
<td>NIH, DTRA, CBMS</td>
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<tr>
<td>Neumedicines</td>
<td>Hematopoietic - HemaMax (rhIL-12)</td>
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<tr>
<td>Arai</td>
<td>Hematopoietic - erythropoietin mimic (small peptide), ARA 290</td>
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<td>NIH</td>
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<tr>
<td>RxBio</td>
<td>GI - lysophosphadtidic acid analog, Rx100</td>
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<tr>
<td>Apogee Biotech</td>
<td>GI - sphingosine kinase (SK) inhibitor, ABC294640</td>
<td>Active</td>
<td>NIH</td>
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<tr>
<td>U Arkansas</td>
<td>GI - somatostatin analog, SOM230</td>
<td>Active</td>
<td>NIH</td>
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<tr>
<td>Avaxia Biologics</td>
<td>GI - orally delivered anti-TNF antibody, AVX-470</td>
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<tr>
<td>Contractor</td>
<td>Area and Description</td>
<td>Status</td>
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<td>Aeolus Pharmaceuticals</td>
<td><strong>Lung</strong> - broad spectrum catalytic anti-oxidant, AEOL 10150</td>
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<tr>
<td>Humanetics</td>
<td><strong>Lung</strong> - BIO 300 (genistein)</td>
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<td>NIH</td>
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<td>US Biotest</td>
<td><strong>Cutaneous radiation injury</strong> - angiotensin analog, NLE-A(1-7)</td>
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<td>NIH</td>
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<tr>
<td>KeraNetics</td>
<td><strong>Cutaneous radiation injury</strong> - KeraHeal – keratin-based hydrogel</td>
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<td>Heyltex</td>
<td><strong>Decorporation Agent</strong> - Prussian blue, pediatric administration (Cs-137)</td>
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<tr>
<td>Nanotherapeutics</td>
<td><strong>Decorporation Agent</strong> - NanoDTPA (oral)</td>
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<td>NIH</td>
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</table>
Timeline Post-Detonation

**0 - 72 hrs**
- Administer fluids
- Secure airway
- Manage pain
- Provide early nutrition
- Prevent wound infection

**72 hrs - Beyond**
- Conclusive burn wound care
- Functional recovery
- Provide fluids & nutrition

**Phase I Products**
*Field Care*

**Burn Wound Treatments**
1. Anti-microbial barrier burn bandages

**Key Complementary Products**
A. Oral rehydration therapy sachets
B. Point-of-care airway management
C. Analgesics (oral/intramuscular)
D. Nutritional supplies (oral)

**Phase II Products**
*Definitive Care*

**Burn Wound Treatments**
2. Autologous-based treatment products
3. Natural biological products
4. Manufactured biological products
5. Anti-microbial burn dressings

**Key Complementary Products**
E. Burn care surgical equipment
F. Rehydration fluids (oral/intravenous)
G. Nutritional supplies (oral/nasogastric)
H. Pharmaceuticals (analgesics, sedatives, systemic antibiotics)
The Nation Needs Accurate Timely Radiation Exposure Diagnostics

• 11 projects awarded to date
  — 10 in FY2010
  — 1 in FY 2011

• 6 projects continuing forward in 2012
  — Biomarker feasibility shown
    • Mouse or human
  — In product development phase
    • Proof of concept complete (TRL4)
    • In product development phase
      — NHP & human biomarker performance
      — Instrument strategies / development
      — Assay development

**BARDA Biodosimetry Program**

**Proteomics**

**Gene expression**

**Electron paramagnetic resonance**

**Ocular screen**

**Volatile organic compounds**

**DNA damage**

**Cytology**

**Assay development**
Bioassay Testing at CDC

- **Capability:** Rapid *screening*, *identification* and *quantitative* assessment of *internal* incorporation of radionuclides to quantify exposure or dose (“health risk”)
  - Provide initial identification of a possible poisoning (e.g. $^{210}$Po)
  - Assist with the EPI investigation

- **Capacity:** ID and Quantify approximately 300 samples per day

- **Dose Range:**
  - 0.0001 to >2 Sieverts (Sv) - analytical sensitivity
  - Medical Treatment Threshold
    - 0.05 Sv Children and Pregnant Women,
    - 0.2 Sv for the general population
## Bioassay Testing at CDC

<table>
<thead>
<tr>
<th>Radionuclides</th>
<th>Urine bioassay detection</th>
<th>Primary radiation detection</th>
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</thead>
<tbody>
<tr>
<td>Uranium ($^{235}\text{U}$, $^{238}\text{U}$), Thorium</td>
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<td>alpha and beta particles</td>
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<tr>
<td>Strontium, Plutonium ($^{238}\text{Pu}$, $^{239}\text{Pu}$)</td>
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<td>Americium, Californium, Neptunium,</td>
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<tr>
<td>Phosphorus, Curium, Polonium</td>
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<tr>
<td>Cesium, Cobalt ($^{57}\text{Co}$, $^{60}\text{Co}$), Radium</td>
<td>yes</td>
<td>Gamma rays</td>
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<td>Iodine ($^{125}\text{I}$, $^{131}\text{I}$), Technetium-99m</td>
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<td></td>
</tr>
<tr>
<td>Selenium, Molybdenum, Iridium</td>
<td>yes</td>
<td></td>
</tr>
</tbody>
</table>

**Internal radiation screening via hand held detectors or portals is only applicable for gamma emitting**
• Listening and responding to our stakeholders’ needs
• With you for Planning, Response and Long-range Recovery
• Adapting to Change