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Product-Specific Requirements for Medical Countermeasures to Symptomatic Individuals Exposed to Smallpox, Botulism and Anthrax

Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Be All End All (BAEA) Integrated Program Team

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Product-Specific Requirements for Medical Countermeasures to Symptomatic Individuals Exposed to Smallpox, Botulism and Anthrax – October 2011

These requirements are approved by the Enterprise Executive Committee of the Public Health Committee of the Public Health Emergency Medical Countermeasures Enterprise, US Department of Health and Human Services.

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The Threat

An earthquake in one of the three U.S. cities where biosafety level 4 pharmacological laboratories are located (Boston, MA; San Diego, CA; Washington, DC) could cause a great number of human casualties, many of which would require medical intervention. In addition to the direct effects of an earthquake (cutaneous burns, smoke inhalation, etc...), biosafety level 4 pharmacological laboratories may sustain damage that causes a breach in containment.

Consequence assessments by PHEMCE experts based on a wide variety of chosen scenarios indicate that up to as many as 300,000 persons would be affected and require medical care, with a low percentage of modeled scenarios having even greater projected consequences. Of all the scenarios that would result in Smallpox, Botulism and/or Anthrax, the worst-case plausible scenario identified would result from an earthquake registering as an 8 on the Richter scale in one of the three previously identified cities. This scenario would require medical countermeasures to treat 300,000. Accommodating conventional standards of medical care under scenarios of this magnitude of destruction would require resources beyond those contemplated in this analysis, and/or alternative approaches to managing the casualties.

The Scenario and Requirements Assumptions

The medical countermeasure requirements expressed in this paper are based on consequence models used to assess multiple potential scenarios, with strategic choice of the requirements based on the amount of the primary resources projected to be required to treat those infected by Smallpox, Botulism and/or Anthrax. Comparing results from multiple scenarios rather than deriving data from a single, potentially idiosyncratic, scenario provides a better understanding of a wide range of potential effects and provides a basis for strategic determination of requirements for medical countermeasures (MCMs). Population densities, effected city geography and infrastructure characteristics (i.e.; building types and materials), and other such factors as the time of day and weather can contribute to considerable variation of outcomes in a model of an earthquake in one of the previously listed cities. Planning to the greatest-consequence scenarios among those considered plausible was considered appropriate as an objective. Alternative approaches could include objective requirements aimed at the vast majority of plausible scenarios excluding the most severe, if costs for most severe are considered prohibitive. The approach here leaves such benefit-cost considerations to be taken into account during the acquisition process.

¹ All numbers provided in this document are estimates and to be used for training purposes only.

Response to a Biological Event

The magnitude of the national security and health consequence of a substantial biological event after an earthquake in the previously mentioned U.S. cities would immediately overwhelm the emergency and civilian response resources of the locale and the region. This is complicated by the loss of infrastructure, including utilities such as water and electricity/gas, media resources such as television and internet, and roads and highways. The threat from the damaged biosafety level 4 pharmacological laboratories would pose a biohazard threat to health and safety as those in the affected area would be at risk to contamination from the biologics (Smallpox, Anthrax and Botulism) contained within the laboratories.

Because of the tremendous destruction and moderate number of casualties resulting from an 8.0 earthquake, emergency response resources in the three previously stated cities and region will initially be overwhelmed. A joint response that integrates missions and assets across all levels of government and the private sector is vital and ethically necessary to maximize the response and save as many lives as possible. The National Response Framework (NRF) recognizes that the integrated emergency response begins with the local and state governments, with support from the Federal Government.² This integrated response must overlay the conditions of the initial earthquake, biohazard area, and other hazards, and thus appropriate allocation of personnel and assets must be within the context of a response that keeps resources in working order and saves lives. The public health and medical component of the response and is managed by the Secretary of Health and Human Services in accordance with the NRF Emergency Support Function #8 (Public Health and Medical Services).³

Patient movement can be complex for patients with severe injuries. This means that medical countermeasures that reduce the inherent complexity of patient management from field collection to hospital bed are particularly favorable. Triage involves cataloging patients according to perceived severity of injury and perceived survivability weighed in light of the available resources (personnel, supplies, equipment, bed-space, etc.).

² The National Response Framework, 2008, US Department of Homeland Security. pg 15-24. see <http://www.fema.gov/pdf/emergency/nrf/nrf-core.pdf>

³ The National Response Framework, 2008, US Department of Homeland Security, Emergency Support Function #8 Public Health and Medical Services Annex, pg ESF#8-2. see <http://www.fema.gov/pdf/emergency/nrf/nrf-esf-08.pdf>

Mechanisms of Injury/Infection

Anthrax Infection

Bacillus anthracis is considered a biological threat agent. *B. anthracis*, the causative agent of anthrax, is a Gram positive sporulating rod. It is a zoonotic disease that is transferred to man the spores or infected tissue or spore-containing materials. The spores are very hardy and persist in the environment for many years. There are three main clinical forms of anthrax infection: cutaneous, gastrointestinal and inhalational. The mortality of particularly inhalation anthrax is high once symptoms begin, but disease can be prevented if antimicrobial prophylaxis is started shortly after exposure to the spores and before a person develops signs and symptoms of disease. Toxemia, due to toxins released by *B. anthracis*, is the major cause of morbidity and mortality for this disease. This form of attack would be odorless and likely invisible and could result in widespread dissemination. The former Soviet Union and Iraq developed and tested large-scale aerosolization techniques.⁴

Following an aerosol-release of *B. anthracis*, spores persist in the environment and contaminate buildings and equipment and may require environmental decontamination. Remediation may require extensive and expensive decontaminating procedures that may have a significant and long-term impact on the ability to return a contaminated site to pre-exposure operating levels as well as significant economic implications.

Smallpox Infection

Smallpox unlike anthrax, is a contagious disease. It localizes in small blood vessels of the skin and in the mouth and throat. In the skin, this results in a characteristic maculopapular rash, and later, raised fluid-filled blisters. *Variola major* produces a more serious disease and has an overall mortality rate of 30–35%. *Variola minor* causes a milder form of disease (also known as alastrim, cottonpox, milkpox, whitepox, and Cuban itch) which kills about 1% of its victims.^{5, 6}

Smallpox virus preferentially attacks skin cells, causing the characteristic pimples (called [macules](#)) associated with the disease. A rash develops on the skin 24 to 48 hours after lesions on the mucous membranes appear. Typically the macules first appear on the forehead, then rapidly spread to the whole face, proximal portions of extremities, the trunk, and lastly to distal portions of extremities. The process takes no more than 24 to 36 hours, after which no new lesions appear.⁶

⁴ Inglesby TV, O'Toole T, Henderson DA, Bartlett, JG, Ascher MS, Eitzen E, et al. Anthrax as a biological weapon, 2002: Updated recommendations for management. JAMA 2002; 287:2236-52.

⁵ Behbehani AM (1 December 1983). "The smallpox story: life and death of an old disease". Microbiol Rev 47 (4): 455–509. PMC 281588. PMID 6319980

⁶ "Smallpox". Armed Forces Institute of Pathology: Department of Infectious and Parasitic Diseases. Archived from the original on 2007-10-09.

http://web.archive.org/web/20071009141639/http://www.afip.org/Departments/infectious/sp/text/1_1.htm. Retrieved 2008-10-28

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Botulism Infection

Botulism is a serious muscle-paralyzing disease caused by a nerve toxin made by the bacterium *Clostridium botulinum*. These bacteria are in soil throughout the world and produce spores that can survive in a dormant state until favorable conditions allow them to grow.

Several terrorist groups and some nations are believed to have or are experimenting with biological weapons programs. Botulinum toxin has been a concern as a potential biological warfare agent since World War II. The extreme toxicity of botulinum toxins and the ease of production, transport and delivery make this a potential bioterrorism agent.

Special Requirements and At-Risk Populations

At-risk populations, those with needs different from those of the general adult population, specifically include children, elderly people, pregnant women, immune-compromised individuals and people with mental or physical disabilities. These particular populations may require special considerations beyond incident-related general medical needs, due to characteristics that differentiate their injury susceptibility and/or ability to receive care from that of the general population.

At-risk populations may have difficulty in accessing care, or special medical conditions that put them at risk, and they may require special considerations for monitoring disease progression and secondary effects on related injuries. For example, people with mental or physical disabilities, while not specifically mentioned in the PAHPA⁸, may have difficulty with both understanding and following instructions or directions, or physical impairments preventing follow-through (such as mobility impairment) so that they do not shelter-in-place effectively.

⁷ "Botulism and Bioterrorism" Texas Department of State Health Services.

http://www.dshs.state.tx.us/preparedness/factsheet_botulism.pdf Retrieved 2010-08-17

⁸ Pandemic and All-Hazards Preparedness Act (109th Congress) § 2802(b)(4)(B) defines "the term 'at-risk individuals' means children, pregnant women, senior citizens and other individuals who have special needs in the event of a public health emergency, as determined by the Secretary [of Health and Human Services]."

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s3678enr.txt.pdf,

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Current and Developmental Medical Countermeasures

Company	Product	Animal Data	IND Filed	Phase 1 Complete	Indications	Formulation and Delivery Route	Treatment Course/Dose
A	Thanatos Vaccine	POC and Animal toxicology Complete and reviewed by FDA	Yes	90% (data analysis underway to complete study report for publication)	Post Exposure to vaccine against Smallpox, Botulism and Anthrax in healthy adults	Lyophilized, injection	20mg 2 doses, 14 days apart
B	Pandora Vaccine	POC and Animal toxicology Complete and reviewed by FDA	Yes	Yes	Pre or post exposure treatment vaccine for Smallpox, Botulism and Anthrax in healthy adults	Liquid Frozen, IV	500 mg
C	Apollo Vaccine	POC Complete, Toxicology underway	No	No	Vaccine/Treatment for exposure to Smallpox, Botulism and Anthrax in healthy adults, pediatrics and geriatrics	Liquid oral, weight based	2 weight based doses, 7 days apart
D	Moirae Vaccine	POC in NHP underway	No	No	Vaccine/Treatment for exposure to Smallpox, Botulism and Anthrax in immune compromised individuals	TBD	N/A

Medical Countermeasure Requirements

Requirements abbreviated in product characteristics table

Product Characteristics

Threshold product characteristics are those qualifications a product must meet to qualify for acquisition with public funds. The evaluation of a target product that meets PHEMCE threshold requirements is driven by objectively weighting favorable characteristics against those less-favorable. Cost versus shelf-life is an example of two characteristics that balance favorability for a particular countermeasure in that high-cost and long shelf-life, or low-cost but short shelf-life, are both balances more favorable than high-cost with short shelf-life, for example. Additionally, while radiation and biologically induced infection pose potentially different requirements, the target profiles below support comorbidity therapies.

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Product Characteristics are as follows:

Key Requirement	Threshold	Objective
Intended Use / Indication (fictitious)	To treat Smallpox, Botulism and Anthrax. Should not have contraindications for special populations (“at-risk”).	To treat Smallpox, Botulism and Anthrax. Should not have contraindications for special populations (“at-risk”) and should meet needs of special populations such as pediatrics, geriatrics and immune-compromised individuals for example.
Efficacy range (fictitious)	Efficacy when first used greater than 24 hours post exposure.	Efficacy when used greater than 72 hours post exposure
Regulatory Status (fictitious)	A FDA-enabled mechanism for use during an emergency, for the treatment of Smallpox, Botulism and Anthrax with no contraindications.	FDA-approved for the treatment of Smallpox, Botulism and Anthrax
Safety (fictitious)	Meets FDA requirements	Meets FDA requirements
Formulation (fictitious)	Any administration is appropriate that has efficacy.	Any administration is appropriate that has efficacy and addresses more preferred characteristics. Ease of administration is preferred, i.e.: simple training
Efficacy (fictitious)	Reduced healing times, reduced pain, and reduction in labor intensive care.	Reduced healing times, reduced pain, reduced labor intensive care, reduced surgical activities, reduced infection, technologies that particularly reduce hospitalization time and reduce labor intensive care, or able to bypass inpatient care.
Utilization Schedule (fictitious)	Prime - boost administration with a maximum of 1 boost within 72 hours due to patient tracking concerns.	One time administration is preferred. The goal is to reduce the labor intensive activities, patient tracking and follow up, and reduce hospitalization time, while enhancing healing.
Stability / shelf-life (fictitious)	24-months with freezing or refrigeration, or expiration that fits within a novel stockpiling strategy.	5-years with freezing, refrigeration, or room temperature conditions, and an alternative stockpiling and utilization strategy to centralized stockpiling.
Storage Conditions / Packaging (fictitious)	Frozen or refrigerated for others such vaccines. Packaging as required by the FDA that is appropriate for storage, tamper-evident, child-resistant.	Ideally at room temperature, including alternative stockpiling/utilization strategy; less energy-intensive storage conditions are preferred (room temperature>refrigeration>freezing) Packaging as required by the FDA that is appropriate for storage, tamper-evident, child-resistant.
Manufacturing (fictitious)	Able to sustain availability of the threshold doses or patient-equivalent courses for other products cumulative over 180 days. Able to surge readily and easily in a relatively short time-frame such as days to weeks.	Able to meet the warm-base requirement or sustain alternative use/storage strategy, meet surge requirements, or meet stockpiling replacement for expired product. “dual-use” is preferred to nuclear specific centralized stockpiling.
Surge Capability (fictitious)	A surge capability to meet the worst case scenario or a negotiated surge capacity under threshold acquisition for dose equivalent within days is preferred.	The objective acquisition is for the full requirement and does not require surge, however negotiations considering other factors may allow for partial acquisition and meeting remaining requirement through surge capacity.
Ease of use (fictitious)	Products that do not require specialized training are preferred. Products that can be applied by medical professionals in accordance with existing standards and practices.	Products easily used and applied with minimal training either by lay people, or medical professionals, products that reduce labor intensive care.

⁹ A pre-EUA is not a mechanism that enables emergency-use, as an EUA must be further “authorized” after a public health emergency is declared. An EUA is a mechanism that could enable emergency-use, however, by itself it is not adequate to meet this criterion, as it requires an additional public health emergency declaration before it can be put in place. It does not exist as a mechanism before an emergency is declared. A mechanism that would be automatically triggered by declaration of a specified type of emergency would meet this criterion, such as an emergency IND that is in place allowing use during an emergency using a specified protocol.



Market Research and Getting Started

Mr. Cameron Hernandez, Program Manager

**Office of Acquisitions Management, Contracts and Grants (AMCG)
Acquisitions Program Support (APS)**



Overview



- System for Award Management (SAM)
- Market Research
- Solicitation
- Getting Started



What is SAM?



- General Services Administration’s (GSA) Office of Government Policy is consolidating government acquisition support systems into one, System for Award Management (SAM).
- Phased Approach
 - Phase I – July 2012
 - Phase 2 – TBD
- Phase I Systems include:
 - Central Contractor Registration (CCR)
 - Federal Agency Registration (FedReg)
 - Online Representations and Certifications Applications (ORCA)
 - Excluded Parties List System (EPLS)
- Phase 2 Systems
 - Subcontracting Reporting System (eSRS)
 - Catalog of Federal Domestic Assistance (CFDA)
 - Wage Determinations On Line (WDOL)
 - Federal Business Opportunities (FBO)

Functional Area	Capabilities	Legacy Systems
Entity* Management	Register/Update Entity core data Manage certifications / representations	CCR/FedReg – Central Contractor Registration/Federal Agency Registration ORCA – Online Representations and Certifications Application
Award Management	Post solicitation and award data Maintain government-wide contract award data Manage government-wide subcontractor data	FBO – Federal Business Opportunities FPDS-NG – Federal Procurement Data System-Next Generation eSRS/FSRS – Electronic Subcontracting Reporting System/FFATA Subaward Reporting System
Wage Data	Access wage determinations	WDOL – Wage Determinations Online
Performance Information	Manage/maintain past performance information Manage exclusion list	PPIRS/CPARS/FAPIIS – Past Performance Information Retrieval System EPLS – Excluded Parties List System
Assistance Program Catalog	Create/maintain assistance program catalog	CFDA – Catalog of Federal Domestic Assistance
Support	Provide security/access control Provide reporting/communications support Provide internal controls	



Who should use SAM?



- Any entity wishing to do business with the federal government under a Federal Acquisition Regulation (FAR)-based contract or applying for federal grants, cooperative agreements or other forms of federal financial assistance through Grants.gov must be registered in SAM. Federal agencies may require entities be registered in SAM for additional processes.
 - Contractors
 - Federal Assistance Recipients and other potential award recipients
 - Government contracting and Grants officials
 - Public users, market research
- How do you get started?
 - WWW.SAM.GOV
 - User Guide can be accessed at [https://www.sam.gov/sam/transcript/SAM User Guide v 1.8.pdf](https://www.sam.gov/sam/transcript/SAM_User_Guide_v_1.8.pdf)

Informal Market Research

- Market Resources

- Google
- SAM
- Publications
 - News, medical and scientific journals, new technology announcements, etc.



- Databases

- Dun and Bradstreet
 - Supplier Risk Manager (SRM)
 - Hoovers
- Library & Information Technology Association (LITA)



- Government Offices

- Current Activities
- Past Performance

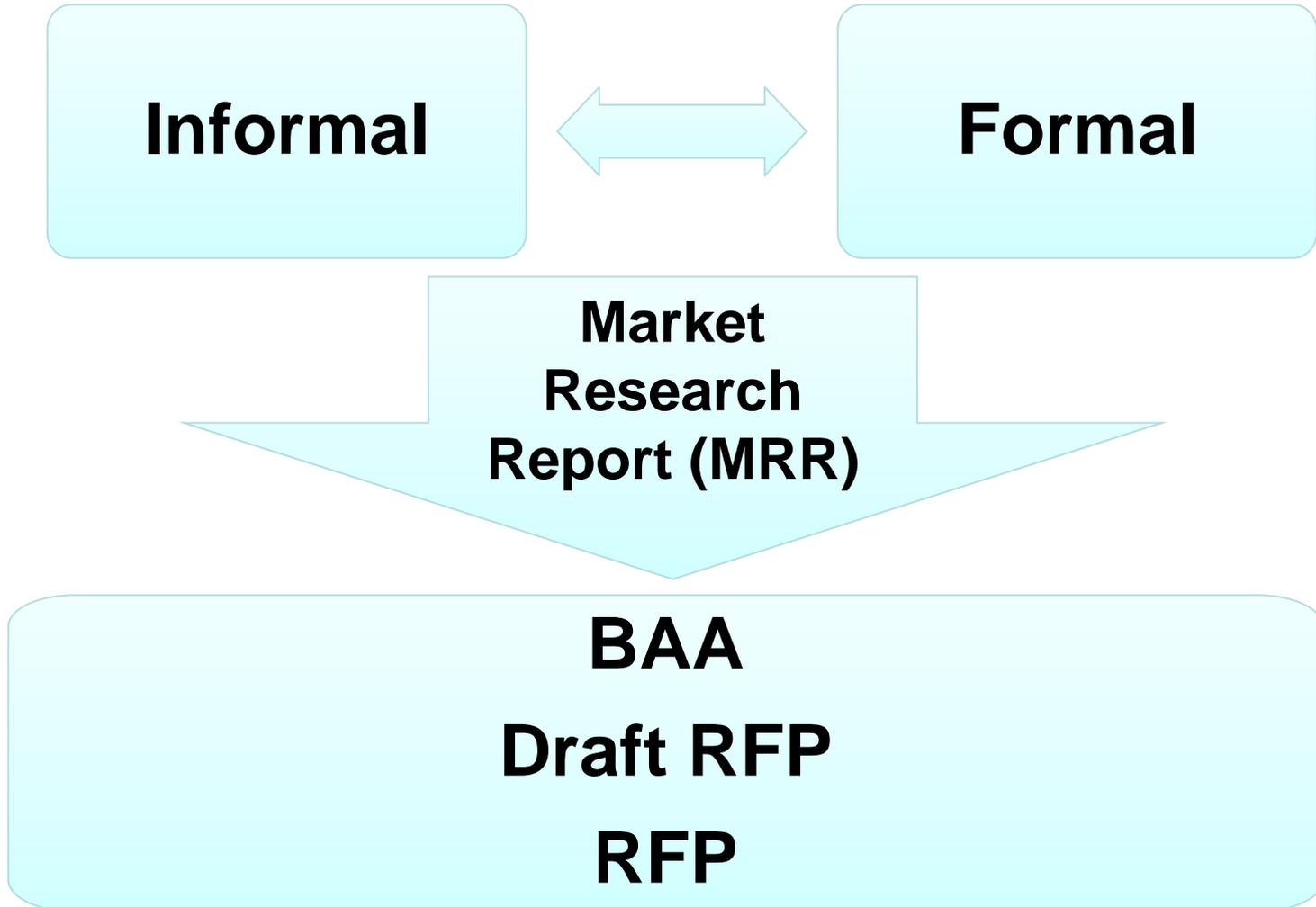


- Conferences/Work Shops
 - BARDA Industry Day, Wash DC 2012
 - PHEMCE Workshop
- Tech Watch
- Sources Sought Notice
- RFI (Request for Information)
- AOA (Analysis of Alternatives)
 - Public Health vs Vaccine
 - Diagnostic + Treatment vs Vaccine
- Draft RFP (Request for Proposal)
- BAA White Papers





Determination to Issue a Solicitation





How does a perspective contractor get started?



- Companies must register with



- Dunn and Bradstreet
- Central Contractor Registration (CCR)

Central Contractor Registration

- Federal Business Opportunities (FedBizOps)



- Public Health Emergency.gov





Company A

1234 Huntington Way
St. Martinville, LA 70582

Company A

- **Company A is a company of about 250 employees, with \$20 million in annual business based upon sales of their FDA licensed anti-viral vaccine XXX and contract services provided to the US Federal Government and other partners. Headquartered in St. Martinville, LA, Company A has access to research centers and has partnered with numerous small, bio-tech companies.**
- **In May of 2008, Company A built in St. Martinville, LA a state-of-the-art 70,000 sq. ft manufacturing facility which has the capacity to handle an influx of 90,000 doses/month. The St. Martinville facility recently acquired a lyophilization unit and fill/finish wing in 2010.**

