



United States Department of
Health & Human Services
Office of the Assistant Secretary for Preparedness and Response



New Paradigm for Preparedness - Development and Acquisition of Radiological and Nuclear Medical Countermeasures (MCM)

**BARDA Industry Day
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Radiation/Nuclear MCM Product Development Strategy



- **Repurpose whenever possible**
 - Leverage drugs that are already approved, licensed, or cleared by the FDA for conventional clinical indications (e.g., treatment of bone marrow suppression in cancer patients).
 - Leverage existing manufacturing capabilities.
 - Expanding an approved product's use to a threat-focused indication often enables a more streamlined regulatory pathway (previous studies can be used to support the new indication).
- **USG stockpiles should take advantage of existing inventories in marketplace**
 - Pursue stock rotation (Vendor Managed Inventory), not warehousing, for MCMs with commercial market demand.
 - Replenishment not necessary, conserves budget
- **Develop MCMs via AR&D only as necessary**



Strategic National Stockpile Utilization **ASPR**

ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE

Conventional strategy to ensure sufficient preparedness.

- Government owned material is readily available for emergencies.
- Inventory must be replaced as it expires, driving up lifecycle costs.
- MCM products with a sustainable commercial market beyond emergency preparedness enable more cost-effective approaches to development and acquisition.
- Alternatively, preparedness can be established simply by bringing the MCM product to market and integrating its use into standard medical care, obviating the challenges associated with stockpiling and deployment.



Stockpiling vs Stock Rotation via Vendor Managed Inventory (VMI)



- **USG stockpiling paradigm is not sustainable in current fiscal environment**
 - Major USG expense in initial product acquisition.
 - Government owns material stored in USG warehouse.
 - Requires major expense and effort to reacquire upon product expiry.
 - Product shelf life determines repurchase frequency.
 - Can lead to fluctuations in inventory/preparedness.
 - May still be necessary for products with insufficient commercial use.





Stockpiling vs Stock Rotation via Vendor Managed Inventory (VMI)



- **Stock Rotation via Vendor Managed Inventory**

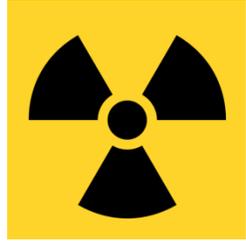
- For products with sufficient commercial market and are used in day-to-day medical situations.
- Initial USG contract is to acquire and manage a specified quantity in inventory. USG does not own a specific lot or batch.
- USG product retained by Vendor as inventory bubble in distribution chain to commercial market. First in, first out.
- USG takes possession from vendor only at time of need.
- Overall lifecycle costs are minimized as USG pays only management expenses to maintain level of preparedness.
- USG material never expires, so no reacquisition costs.

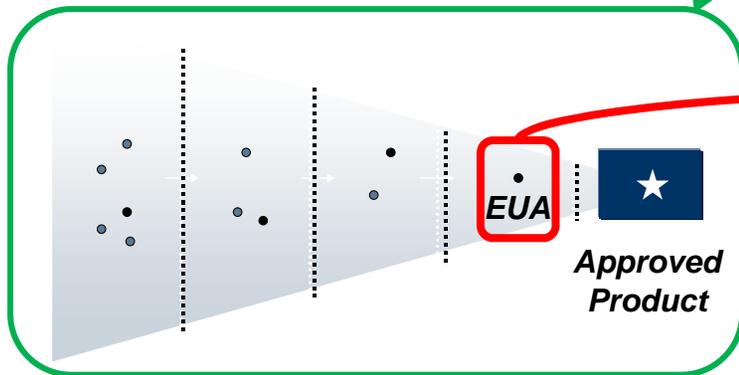




Strategy for use of VMI: Neupogen™ and other similar cytokines



	Field Care (First 72 hours)	Definitive Care (After 72 hours)
 Acute Radiation Syndrome	H-ARS	H-ARS
	GI-ARS	GI-ARS
	Lung-ARS	Lung-ARS
	Cutaneous Injury	Cutaneous Injury



- **Neupogen™** (filgrastim) has pre-EUA determination from FDA
- FDA-approved for related indication (febrile neutropenia in patients being treated with anti-cancer drugs)





Proposal and Successful Implementation of VMI



Request For Proposal (RFP)-12-100-SOL-00016:

- **Acquisition and Advanced Development of a Colony Stimulating Factor (G- or GM-CSF) for Mitigation of Neutropenia Arising from Exposure to Ionizing Radiation**
 - RFP issued in 2012
 - Awards issued Sept 19, 2013 for acquisition and inventory management for both G-CSF and GM-CSF medical countermeasures.



RFP-12-100-SOL-00016



- **Services:** A vendor-managed inventory with rotation of stock to control product expiry. The inventory management plan shall also include a plan for rapid “at need” United States Government (USG) access to product at the contractor’s storage facility(s) should the USG have an immediate need for access to product in an emergency situation.
- These contracts established the Vendor-Managed Inventory (VMI) requirements under which the Contractor shall maintain and provide availability of the products and quantities 24 hours a day, 7 days a week (24/7).



Thank You