Continuation Guidance – Budget Year Five
Attachment J
CHEMPACK Program Description

Participation in CHEMPACK is strictly voluntary for public health agencies. Keep in mind, however, there are other entities in the state that might choose to participate even if the public health department chooses not to (e.g., emergency management).

Jurisdictions receiving the CHEMPACK must ensure that the storage locations be of a suitable size, designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, and security conditions for storage of pharmaceuticals.

Based on a pilot study conducted in New York City, South Dakota, and Washington State, the average cost for CHEMPACK container storage is expected to be approximately $2,000 to $2,500. It is imperative that Public Health work in collaboration with the appropriate Emergency Response Agencies to implement the CHEMPACK program.

Funding for the initial CHEMPACK installation and sustaining cost can be defrayed by a variety of funding sources including local, state, other federal such as HRSA or MMRS, and private funds.

Recipients of funding through the Cooperative Agreement for Public Health Preparedness and Response for Terrorism can also request redirection of current year funds or carry over un-obligated prior-year funds, to support the costs associated with receiving and managing CHEMPACK materiel. Redirection and carryover requests must contain a statement listing which program activities will not be completed if the request is approved. All requests must be forwarded to the CDC Procurement and Grants Office (PGO).

Questions related to cooperative agreement funds should be directed to the appropriate project officer in the OTPER Division of State and Local Preparedness.

Strategic National Stockpile Program (SNS)
Office of Terrorism Prevention and Emergency Response (OTPER)
Centers for Disease Control and Prevention (CDC)

CHEMPACK PROJECT

Operational Protocol

Background

Terrorist attacks against United States citizens and US interests around the world culminated in the mass destruction of the World Trade Center and damage to the Pentagon on September 11, 2001. Intelligence sources believe that terrorist groups will continue their destructive activities and may use unconventional weapons in order to maximize casualties. To defend against these threats, planners and responders must be able to quickly mobilize resources to minimize and mitigate the effect of a nuclear, biological, chemical, or radiological terrorist attack. While preventing such an event is the primary goal, it is probable that not all terrorist efforts can be stopped. In the aftermath of a weapon of mass destruction (WMD) event, first responders will focus on response activities designed to mitigate morbidity, mortality and destruction of property.

One scenario involves terrorists using chemical weapons. Terrorist organizations may have access to many different types of chemical agents to use in WMD attacks. The likely choice may be nerve agents. Depending on the dose, nerve agents can cause immediate nervous system failure and death. Nerve agent antidotes include:

- Atropine sulfate, which blocks the effects of excess acetylcholine at its site of action;
- Pralidoxime chloride (2PAM), which reactivates acetyl cholinesterase, and therefore reduces the levels of acetylcholine; and
- Diazepam, which reduces the severity of acetylcholine-induced convulsions that can contribute to death or long term neurological effects in survivors.

The SNS Program has numerous caches of medical equipment, pharmaceuticals and vaccines in strategic locations throughout the United States, including the medicines described above. Under its mandate, the SNS Program has a maximum 12-hour response time. However, this response time is inadequate for a nerve agent event, where treatment must be accomplished quickly in order to save as many lives as possible.

As a result, the Centers for Disease Control and Prevention has established a voluntary participation project (CHEMPACK) for the “forward” placement of sustainable repositories of nerve agent antidotes in numerous locations throughout the United States, so that they can be immediately accessible for the treatment of affected persons. Under this project, the SNS Program will:

- maintain ownership of the CHEMPACK stockpile;

- in conjunction with state and local officials, place the antidotes in numerous strategically placed containers under controlled and monitored storage conditions for use in the event of an emergency involving nerve agents .;
- implement strategies to maximize the shelf life of the antidotes to minimize re-procurement costs and maintain quality, specifically through the Federal Drug Administration's (FDA) Shelf Life Extension Program (SLEP).

This approach allows the SNS Program to maintain accountability and the centralized control of the caches to fulfill the criteria for the SLEP program while making the caches immediately available to state / local authorities in case of an actual event involving nerve agents. To meet the objectives of CHEMPACK deployment, states / cities (i.e., CDC 62 BT Project recipients) and the SNS Program incur specific responsibilities as set forth below.

State and Local Responsibilities

The state / city will provide overall management of the state / city-wide CHEMPACK Project and will oversee the receipt, storage, monitoring, maintenance and potential deployment of CHEMPACK assets.

The state / city will:

1. agree to authorize breaking the CHEMPACK container seal and making use of the packaged products only when it is determined that an accidental or intentional nerve agent release has threatened the public health security of the community. Providing treatment to the American people after a nerve agent incident through CHEMPACK Project assets is very expensive. The project will remain economically feasible only if its materiel is used prudently and maintained under conditions that allow the SNS Program to extend its shelf-life in cooperation with the FDA. Therefore, the undersigned agrees to maintain unbroken the seal on all CHEMPACK containers and use project materiel only when it determines that other means to save human life will not be sufficient. For instance, if a farmer is overcome by exposure to insecticides and can be saved by using local antidotes to treat the exposure or by a life-flight helicopter ride to a facility that has the antidotes, the undersigned will elect that option in preference to breaking the seal of a CHEMPACK container and using its materiel (an action that would prevent the SNS Program from extending the shelf-life of unused material in the container).

2. designate a single and specific state / city wide point of contact (POC) for CHEMPACK.

3. determine the quantity and type of CHEMPACK containers (EMS / Hospital), required to meet the needs of state and local first responders to respond to a nerve agent event within stipulated budget constraints;

4. provide the address of each cache storage location and ensure coordinated access to SNS Program personnel to cache locations as needed to monitor CHEMPACK materiel and;

5. develop plans for CHEMPACK Project deployment, surveillance and maintenance operations.

6. identify a pharmaceutical or medical professional with a DEA registration at each cache storage location who will sign for and accept custody of the Scheduled IV narcotics and other pharmaceuticals in the CHEMPACK containers. That person will be responsible for the storage and safeguarding of the DEA compliant container in the facility and ensure compliance with applicable local, State and Federal Regulatory guidelines. The SNS Program retains ownership of the CHEMPACK materiel and will ensure the integrity of the pharmaceuticals for the Shelf Life Extension Program.

The state / city will ensure the provision of the following facilities or conditions for each CHEMPACK cache storage location.

A. Container Storage

1) The state / city shall require that cache storage locations be of a suitable size, designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, and security conditions for storage of pharmaceuticals and conform to standards in reference B. This will generally include:

   a) provide a locked room or cage. The CHEMPACK container is constructed of Lexan® mesh and is approved by the Drug Enforcement Agency (DEA) for storage of Class IV controlled drugs. For this reason, there is no requirement for floor to ceiling construction. The purpose of the enclosed room or cage is to control access and ensure compliance with applicable Federal, State and Local pharmaceutical regulations.
   b) install an intrusion detection device, directed towards the CHEMPACK containers, to alert cache location security or pharmacy personnel of possible intrusion into the storage area. The sensor must be physically monitored on a 24-hour basis by security or pharmacy personnel. Cache location security managers will test the interior devices according to manufacturer specifications to ensure proper operation.
   c) ensure a minimum clearance of 72” aisles and 45” doorways to maneuver containers in and out of the storage location.
   d) provide a minimum of 50 sq. ft. of floor space per container at each cache location.
   e) ensure accessibility to CHEMPACK containers. CHEMPACK container dimensions are 64” long X 44” wide X 60.5” high and weigh 500 - 700 pounds.
   f) ensure CHEMPACK containers are stored in a climate-controlled environment with a thermostat that automatically maintains room temperature between 59 to 86 degrees Fahrenheit (15 degrees and 30 degrees Celsius). Humidity must be maintained below 60% to prevent visible mold growth.

g) provide one dedicated data quality analog phone line per Sensaphone® (this line may not be a shared line).
h) ensure one dedicated standard 120VAC, 60HZ, 10W, UL-listed power outlet and a back-up power source per Sensaphone® (uninterruptible power supply (UPS) or existing facility emergency generator is adequate).
i) ensure each container is locked with a padlock and access to the key is limited; key control shall be the responsibility of the cache location pharmacy director.
j) provide a fire detection and alarm device and, adequate fire suppression in accordance with applicable Federal, State and Local pharmacy regulations and fire codes.
k) provide standard lighting to ensure CHEMPACK personnel can clearly see lot numbers and product expiration dates as required by applicable Federal, State and Local pharmacy regulations.
l) ensure proper disposal of expired CHEMPACK medical materiel not in the SLEP program; upon material replacement by SNS personnel.

2) The state / city shall identify a pharmacy or medical professional with a DEA registration at each cache location to sign for and accept custody of the Scheduled IV narcotics and other pharmaceuticals in a CHEMPACK container.

B. Quality Control

The state / city shall require each cache storage location to designate:

1) personnel to conduct joint inventories and monthly security checks to visually inspect SNS Program seals on the CHEMPACK containers (in accordance with applicable Federal and State regulations the person signing for custody must be a Registered Pharmacist or his / her designee); and

2) personnel to conduct quality control checks at each cache location to ensure that the climate is within acceptable environmental limits and to send a quality control (QC) report to SNS Program each month or as requested by SNS Program to document storage conditions at each cache location.

C. Correct Out-Of-Compliance Conditions

The state / city shall ensure cache storage locations apply resources and assets to correct non-complying environmental and security conditions in a timely manner (usually within two hours). When conditions cannot be corrected within 12 hours, the State CHEMPACK point of contact will coordinate with the SNS Program point of contact for movement of the CHEMPACK container(s) to an acceptable location to protect the quality or security of the materiel.

SNS Program Responsibilities

The SNS Program will:

1. Establish a maximum number of caches the State may have in order to maintain acceptable cost savings under the Shelf Life Extension Program (SLEP). Refer to http://www.jrcab.army.mil/fda/page1.html .

2. Develop standardized container packages with a treatment formulary to treat patients for nerve agent exposure, using exposure rates of 30% mild, 40% moderate, and 30% severe.

3. Deliver the CHEMPACK materiel to state designated cache storage locations; once the state has identified the required number and type of CHEMPACK containers EMS or Hospital. The materiel will be maintained in CHEMPACK containers equipped with a Sensaphone®, back-up monitoring system, instructions on how to read the back-up climate control monitoring system, and serial numbered container seals.

4. Provide DEA approved storage containers to hold CHEMPACK materiel.

5. Provide an SNS Program fielding team to install the CHEMPACK containers at state designated cache locations, conduct a joint inventory with designated cache location personnel, and validate the operational status of CHEMPACK environmental and security monitoring equipment.

6. Ensure the schedule IV drugs are secured in a locked DEA approved CHEMPACK container, monitoring devices are operational, and the designated pharmacy or medical professional with a DEA registration has inventoried and assumed custody of the materiel.

7. Retain ownership of all CHEMPACK materiel to ensure the integrity of the pharmaceuticals for the SLEP, until or unless the CHEMPACK is used.

8. Provide resources and assets required to sample, restock, re-label, and dispose of CHEMPACK materiels subject to the SLEP.

9. Provide resources and assets required to perform surveillance and QA/QC of CHEMPACK assets over the life of the Project.

10. Conduct periodic quality assurance and quality control inspections to verify inventory, storage conditions and security of CHEMPACK materiel.

Provisions

1. The SNS Program will not automatically replace any CHEMPACK materiel used in response to an actual nerve agent event. Replacement of materiel lost due to natural

disasters, accidents, or negligence will be negotiated between the State and the SNS Program.

2. Once the State has broken the SNS Program seal on a CHEMPACK container the medical materiel in that container is no longer eligible for the SLEP program.

3. CHEMPACK containers may be moved preemptively to facilitate response during state designated special events, with the following stipulations:

   - The State / city CHEMPACK POC or backup must notify the SNS Program at least 48 hours prior to the preemptive movement of CHEMPACK containers.
   - All movements of CHEMPACK materiel not specifically directed by the SNS Program shall be funded by the State.

4. The state / city must notify the SNS Program CHEMPACK Logistics Team within two hours if a CHEMPACK cache storage location loses climate control.

Resources

1. Funding for the initial CHEMPACK installation and sustaining cost can be defrayed by a variety of funding sources including local, state, and other federal such as DHS, DOJ, MMRS, and private funds.

2. State Public Health Departments receiving funding through the Centers for Disease Control and Prevention (CDC) Cooperative Agreement for Public Health Preparedness and Response for Terrorism (BTCA) are encouraged to request redirection of current year funds or carry over unobligated prior-year funds, to support the costs associated with receiving and managing CHEMPACK materiel. Redirection and carryover request sshould be sent through normal channels to the CDC Procurement and Grants Office (PGO). Questions related to CDC BT cooperative agreement funds should be directed to the appropriate project officer in the Office of Terrorism Preparedness and Emergency Response (OTPER) State and Local Preparedness Program (SLPP).

3. The HRSA National Bioterrorism Hospital Preparedness Program (NBHPP) has joined with the SNS Program CHEMPACK Project to support cache build-out. NBHPP funds earmarked for Medications and Medical supplies may be used to offset reasonable costs associated with the retrofit of CHEMPACK cache storage facilities to meet FDA / SLEP requirements. Questions related the use of these funds should be directed to the HRSA Coordinator in your state or directly to HRSA NBHPP.

4. The states / cities will not be responsible for any costs related to the CHEMPACK containers/chemical antidotes, or transportation cost for initial instillation. The SNS Program will allocate CHEMPACK containers to states and cities, based upon their population (2000 US Census).

Points of Contact

For SNS Program: David E. Adcock, CHEMPACK National Coordinator, CHEMPACK program; voice (404) 687-6750; Fax: (404) 687-6760, email: DEA1@CDC.gov or John Michaels, CHEMPACK Program Manager, voice: (404) 687-6507; Fax: (404) 687-6758; email: JMichaels@CDC.gov.