Q1: What is the DSNS CHEMPACK Program?

A1: The CHEMPACK Program is designed to provide state and local governments a sustainable resource of "forward" placed nerve agent antidotes that will greatly improve their capability to respond quickly to a nerve agent incident. State and local government participation in the CHEMPACK Program is voluntary. Participation in the CHEMPACK Program is not federally mandated. The CHEMPACK program has three main goals.

1. Forward place CDC owned nerve agent antidotes in each project area.
2. Provide project areas a sustainable supply of nerve agent antidote through the Shelf Life Extension Program (SLEP).
3. Provide a cost effective strategy that will save lives through the availability of prepositioned nerve agent antidotes.

Q2: What does CHEMPACK mean?

A2: CHEMPACK is the name given to a sustainable repository of nerve agent antidotes to care for individuals exposed to nerve agents, including but not limited to auto-injectors, bulk symptomatic treatment supplies, and self-monitoring storage containers.

Q3: What is meant by the "Forward" placement of nerve agent antidotes?

A3: If lives are to be saved during and following an attack or the unintentional release of nerve agents, a sustainable supply of antidotes must be readily available to treat victims within minutes of exposure. The CHEMPACK Program assists states and local governments by pre-positioning nerve agent antidotes at hospitals and emergency facilities for use by emergency medical staff and first response personnel. The forward placement of CHEMPACK products provides a supply of nerve agent antidotes for use by first responders to aid exposed individuals

Q4: What is included in a CHEMPACK Container?

A4:

CHEMPACK Container Contents			
Product	Unit Pack	Cases per EMS Container	Cases per Hospital Container
Mark 1 auto-injector	240	5	2
Atropine Sulfate 0.4mg/ml 20ml	100	1	9
Pralidoxime 1gm inj 20ml	276	1	10
Atropen 0.5 mg	144	1	1
Atropen 1.0 mg	144	1	1
Diazepam 5mg/ml auto-injector	150	2	1
Diazepam 5mg/ml vial, 10ml	50	1	13
Sterile water for injection 20cc Vials	100	2	28
Approximate treatment capacity (depending on severity of event)		454	1,000

Q5: How often are the CHEMPACK container medical products rotated?

A5: The goal of the CHEMPACK program is to visit each cache site every 18 months. The frequency of the visits is dependant upon many variables such as: Product availability from the manufacturer, FDA testing and vendor relabeling processes associated with the Shelf Life Extension Program (SLEP), DEA controlled substances inventory requirements, State and Local personnel and facilities availability, CHEMPACK program scheduling requirements and the various expiration dates associated with the eight different products in each container. On the average, new nerve agent antidotes remain effective for 3-5 years. However, using FDA's SLEP, the CHEMPACK Program is able to extend the shelf life of these drugs for **two year increments over three cycles (six total years)** (subject to product efficacy test results every two years).

Q6: How was the breakdown or number of each type of container determined for a Project Area?

A6: Each Project Area was provided an allotment of containers based upon their year 2000 U.S. census population number and the original federally funded budget amount for the entire program. From this allotment each Project Area determines the number of each type (EMS or Hospital) container that best augments their emergency response and preparedness level for their particular situation as supported by their existing Emergency Response Plans. After the year 2010 U.S. census population numbers become available, the CHEMPACK program will seek guidance on the potential for container allocation changes. The potential outcomes for project area population changes are: 1) Proportionate container increases based upon additional federal budget dollars; 2) Realignment of the current number of containers or 3) No changes to the program.

Q7: What are the requirements for Cache Storage Locations?

A7: Each cache location must meet the following general specifications; additional specification may be required based on an on-site inspection of the individual cache site. Project Areas are requested to have alternative locations available for unforeseen circumstances (i.e., Act of God, floods, power failure, etc.).

1. Provide a locked room or cage for storage of CHEMPACK Containers and CHEMPACK Assets for the purpose of controlling access and ensuring compliance with applicable federal, state, and local regulations.
2. Install and monitor on a 24-hour basis an intrusion detection device that alerts RECIPIENT personnel of intrusions or attempted intrusions into the secure storage area.
3. Conduct and record monthly security checks to visually inspect and confirm the integrity of CHEMPACK container seals. All security check records will be made available to the CDC during the on-site inspections and sustainment visits.
4. Ensure each CHEMPACK Container is locked with a CDC-provided padlock and key access is limited to personnel authorized by RECIPIENT's DEA-registrant and/or the Cache location pharmacy director.
5. Maintain minimum aisle widths of 72", door widths of 34", and other clearances to allow easy access to and maneuvering of CHEMPACK Containers.
6. Equip Cache Locations with appropriate equipment and structures (e.g., hydraulic lifts, forklifts, loading docks, ramps) for rapidly accessing, moving, and transporting CHEMPACK Containers.
7. Store CHEMPACK Containers in a thermostatically temperature controlled environment meeting the current United States Pharmacopeia definition of Controlled Room Temperature that encompasses the usual and customary working environment of 20°C to 25°C (68°F to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C (77°F); and that allows for excursions

between 15°C and 30°C (59°F and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range (≤77°F, 15°C), transient spikes up to 40°C(104°F) may be permitted if the manufacturer so instructs. An article for which storage at controlled room temperature is directed may, alternatively, be stored and distributed in a cool place, unless otherwise specified in the individual monograph or on the label. Cool Room Temperature is any temperature between 8°C and 15°C (46°F and 59°F). An article for which storage in a cool place is directed may, alternatively, be stored and distributed in a refrigerator, unless otherwise specified by the individual monograph.

8. For use with the temperature and security monitoring device, maintain: (1) one dedicated 120VAC, 60HZ, 10W, UL-listed power outlet connected to an existing facility emergency generator or other Uninterrupted Power Supply (UPS) device; and (2) one dedicated, unshared Plain Old Telephone Service (POTS) data quality analog phone line or a CAT 5 internet access line as required for the CDC provided temperature and security monitoring device.
9. Maintain the CHEMPACK Containers and CHEMPACK Assets in buildings and facilities that provide proper design and construction; lighting; ventilation, air filtration, and air heating and cooling; plumbing; sewage and refuse; watching and toilet facilities; sanitation; and maintenance in accordance with 21 CFR §§ 211.42 - 211.58.
10. Maintain fire detection and alarm systems, and fire suppression systems as required by federal, state, and local pharmaceutical regulations and fire codes.
11. Store only CDC-provided CHEMPACK Assets in CHEMPACK Containers; storage of non-CDC-provided assets in CHEMPACK Containers, including state-owned nerve agent antidotes, is not permitted.

Q8: Should each project area develop an MOA with each storage location?

A8: A written agreement in the form of a MOA is always a good idea and may avoid future misunderstandings between the project area and their designated cache locations. It is suggested that each project area check with their legal counsel for guidance on how best to develop such working agreements.

Q9: Can the CHEMPACK Containers be temporarily moved for special events?

A9: The Project Area may temporarily transport CHEMPACK Containers for Project Area - or federally-designated special events (e.g., National Special Security Events, Super Bowl, World Series, major political conventions, State fair, etc.) for the purpose of strategically locating CHEMPACK Containers, subject to the following conditions:

a. The Project Area representative must notify CDC at least 48 hours prior to such movement.
b. The Project Area representative's notification must be made telephonically or in writing to the designated CDC CHEMPACK Program Preparedness Branch program consultant AND the CHEMPACK Regional Team Lead.
c. The Project Area representative must maintain temperature and security requirements described in FAQ #7.
d. The Project Area representative assumes responsibility for all costs associated with transport of CHEMPACK Containers not specifically directed by the CHEMPACK Program.

Q10: How do project areas plan for and request to permanently move a CHEMPACK container from one location to another?

A10: Project Areas will ensure the new site meets the requirements listed in FAQ #7 prior to requesting to move CHEMPACK container(s). Once confirming the new site is acceptable the Project Area

representative will contact their CHEMPACK regional team lead by either phone or email at least 30 days prior to the requested move date. The regional team lead will work with the project area to survey the site by either sending CHEMPACK personnel or provide guidance to the project area in performing the survey. Once these preliminary steps are completed a move date will be scheduled. The regional team lead is responsible for notification of all involved parties, a Task Order for external cache site moves or email for internal cache site moves. The Project Area or cache site representative will contact the regional team lead on the day of the scheduled move before and after container(s) movement. Please note any costs associated with preparing the new site or transporting the container(s) is the responsibility of the project area. The cost for transporting container(s) can be mitigated if the container move is coordinated in conjunction with a scheduled Project Area sustainment.

To assist the CHEMPACK program with reducing the number of federal travel days, a project area/cache site that is planning a move, hospital closure or renovation should notify the CHEMPACK representative during the CHEMPACK sustainment in order for the new location to be surveyed 12 months in advance of the anticipated container move.

Q11: What will happen if an item is removed from the CHEMPACK Container?

A11: The Project Area will maintain the integrity of the CHEMPACK Container seal until authorized state or local officials determine that a deployment to respond to a nerve agent release is warranted. The Project Area may deploy CHEMPACK Assets in response to nerve agent events that: (1) threaten the medical security of the community; (2) put multiple lives at risk; and (3) are beyond local emergency response capabilities. The Project Area representative will notify CDC within 24 hours of a deployment and report the types and amounts of CHEMPACK Assets: (1) removed and used in the deployment; (2) returned to the CHEMPACK cache site location. CDC will reseal the container following a joint inventory conducted by CDC and the RECIPIENT.

Q12: What is the best way for CHEMPACK containers to be moved during a response?

A12: Both the Hospital and EMS CHEMPACK containers are designed to be easily moved using standard warehouse and commercial transport equipment. Containers are designed to be moved by pushing, pulling (each container has four casters), mechanical pallet jacks, or mechanical forklifts. They can be placed within helicopters or "sling-loaded" below a helicopter. Because the containers are designed for transport by standard airfreight commercial carriers, they can be placed within aircraft designed to transport airfreight. It should be noted that the standard CHEMPACK container will load onto a ½ ton pickup if necessary. Also, the materiel within a container can be removed from the container and placed into a police cruiser or similar vehicle for transport during a nerve agent event. The key issue is the flexibility and rapid access to the nerve agent antidote products that are required by hospital and emergency response professionals to save lives.

Q13: Is there more than one type of CHEMPACK Container design and how much does each weigh?

A13: Currently the CHEMPACK Program has both SATCO® B & C Drug Enforcement Agency (DEA) containers. The dimensions of the DEA approved Lexan® Satco C containers are 60.5" long X 32.5" wide X 60.5" high with a lift off door that measures 52.0" wide and 51.0" high. The Satco B containers are 60.5"" long x 43" wide x 64.5" high with a lift door that measures y" wide and y" high. The Hospital and EMS containers will have different weights because of the configuration of nerve agent antidotes (i.e., unit-of-use, auto-injectors vs. multi-does-vials, and IV solution). Both

the Hospital container and the EMS container weigh between 500-800 pounds each. The containers have a maximum gross weight (with cases) of 1,200 pounds.

Q14: Who determines when a CHEMPACK Container can be opened?

A14: The basic concept of the CHEMPACK Program is that nerve agents must be administered within the first few minutes after exposure if they are to save lives. For that reason nerve agent antidotes must to be readily available (i.e., forward placed) where they are easily accessible to local emergency medical service professionals (EMT) and to hospital emergency room doctors and nurses at the first response level. The decision (to break open a CHEMPACK container) must be delegated/granted to the lowest level of the hospital/emergency response. The Project Area may deploy CHEMPACK Assets in response to nerve agent events that: (1) threaten the medical security of the community; (2) put multiple lives at risk; and (3) are beyond local emergency response capabilities. CHEMPACK material is to be regarded as a secondary response capability and used in the event local supplies are not able to meet treatment requirements.

Q15: Under what conditions does the Sensaphone send an alarm to the CDC?

A15: A Sensaphone is a programmable smart-modem that is specifically designed to report temperatures and container intrusion directly to the CHEMPACK Program at CDC in Atlanta. Once a sensor has identified an "out-of-range" condition (i.e., temperature less than 46 degree or more than 86 degree or a door open indication) the Sensaphone reports directly to the Division of Strategic National Stockpile (DSNS) Maintenance team an alert status to that specific container. There are only four (4) conditions under which a Sensaphone will alert the DSNS Maintenance team: (1) loss of power to the Sensaphone; (2) "out-of-range" temperature; (3) removal of the container door; and (4) disconnection of the phone line. Additionally, Mean Kinetic Temperature (MKT) is monitored on a monthly basis and must not exceed an annual average temperature of 77°.

Q16: What is the CHEMPACK Protocol for notifying the cache site of a Sensaphone alert condition?

A16: A member of the DSNS Maintenance team will contact the cache site representative and inform them of the alarm, and explain the initial assessment of the problem. The DSNS maintenance technician will continue to monitor the site until issues are corrected. If the cache site representative is not available or the problem is not corrected in a timely manner, the DSNS maintenance technician will contact the CHEMPACK fielding team lead who will then contact the Project Area representative for problem resolution.

Q17: Are cache sites permitted to store items on the top of a CHEMPACK container?

A17: Yes, CHEMPACK permits items to be stored on the top of CHEMPACK containers granted the following three (3) conditions are met: (1) the items do not negatively affect the ambient temperature of the cache site, (2) weigh a total of less than 100 lbs and (3) do not inhibit a responder's ability to move or open the container. Items such as pesticides, solvents, petroleum products and flammable materials are not permitted to be stored on or around the CHEMPACK container.

Q18: Are project areas permitted to add labels to the cases prior to them being loaded into the container?

A18: Yes, CHEMPACK permits project areas to use labels to mark the cases for distribution or other response related purposes. Project area labels may not cover any of the existing case labels and they must be applied by project area personnel. CHEMPACK personnel are not able to assist with this process. Additionally, no writing is allowed on the cases with any type of marking pen or pencil.

Q19: Does the CDC provide training on administering CHEMPACK product or developing Project Area response plans?

A19: The CDC and the CHEMPACK program do not provide training on use of CHEMPACK product or developing response plans due to the wide variation of clinical and response requirements in each of the 54 project areas. However, there are resources available on the CHEMPACK SharePoint™ site for reference and training purposes that have been provided as "best practices" by other Project Areas. To use the CHEMPACK SharePoint™ site you must register and be approved by your project area's main CHEMPACK point of contact. You may request access using the following address: http://www.orau.gov/chempack/. It is understood that hospital/emergency response plans must be developed and exercised if they are to be effective. Practice/exercises will identify deficiencies in planning and will assure the effective use of antidotes within the CHEMPACK containers.

Q20: What are CHEMPACK's plans now that Mark I auto injectors are no longer being manufactured?

A20: CHEMPACK plans to eventually phase out Mark I kits and replace with DuoDote™. However, we do not anticipate adding DuoDote™ to the CHEMPACK containers until 2014 at the earliest. We currently have a significant amount of Mark I kits with expiration dates out to 2014. Furthermore we have access to additional kits that can be extended through the Shelf Life Extension Program (SLEP) until 2017. We will provide updates as changes occur with our inventory plans.

Q21: What are CHEMPACK's plans for Sensaphone™ monitoring devices as plain old telephone service (POTS) lines will likely be phased out in the future.

A21: The Division of Strategic National Stockpile is currently searching for a suitable replacement device. The new device will take advantage of a CAT 5 internet line technology. We anticipate the selection of a new device by the end of calendar year 2011 with follow on Sensaphone™ device replacement over a 12 to 24 month period. Additional information will be provided to project areas through regional fielding team leads, CHEMPACK newsletter bulletins and the SharePoint™ site.

Q22: What is Mean Kinetic Temperature (MKT) and why are cache site temperature ranges based on this measurement?

A22: MKT is a fixed temperature that simulates the effects of temperature variation over a period of time. It differs from other means such as a simple numerical average or arithmetic mean in that higher temperatures are given greater weight in computing the average. CHEMPACK cache sites are required to meet United States Pharmacopeia (USP) standards for temperature monitoring in pharmaceutical storage. This standard encompasses "controlled room temperature (CRT)" to be between 20°C to 25°C (68°F to 77°F); that results in a MKT calculated to be not more than 25°C (77°F) over a 365 day period; and that allows for excursions between 15°C and 30°C (59°F and 86°F)