New York State Department of Health

CHEMPACK GUIDELINES

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CHEMPACK PROJECT GUIDELINES

New York State Department of Health

1.0 Historical Perspective

The toxic effect of nerve agent or organophosphate exposure requires immediate pharmaceutical intervention followed by long-term care. This pharmaceutical intervention must be supported in both the pre-hospital and hospital response. The ability of emergency medical personnel to begin immediate treatment of exposed individuals will directly impact a casualty's ability to survive the exposure.

The Centers for Disease Control and Prevention's (CDC) CHEMPACK Program is a nationwide initiative for the placement of nerve agent antidotes in local communities. The CHEMPACK program fills a void in emergency preparedness by placing timely, critical and life-saving antidotes in communities where they will be readily available to emergency medical responders. A CHEMPACK container is a cache of nerve agent antidotes placed in centralized locations to assist first responders to quickly administer life-saving medical countermeasures (MCM) and save lives. Divided into two types of containers: hospital containers configured to treat 1000 victims and EMS containers configured to treat 454 victims, these assets provide participating states and local governments with a sustainable resource to improve their response capability. All containers are owned, maintained and managed by the Division of Strategic National Stockpile (DSNS) to the 62 participating project areas that receive funds from CDC's Public Health Emergency Preparedness Cooperative Agreement.

Voluntary participation in the program required participating project areas to meet the following criteria:

- Designate a lead agency and a point of contact to work with CDC/DSNS staff
- Identify and maintain secure and climate controlled storage sites that best support their emergency response plan
- Integrate CHEMPACK assets into their all-hazards response plan
- Identify a Drug Enforcement Agency (DEA) registrant to accept custody of CHEMPACK materiel

2.0 Introduction

2.1 *Purpose* This guideline is designed to assist Emergency Response Planners in the planning and integration of CHEMPACK Project material into existing *Emergency Response Operations*. This guideline provides background information, program policies, requirements, methodology and blank forms that Counties, local governments, and hospitals may find useful when developing their own CHEMPACK procedures.

2.2 *Background* The New York State Department of Health (NYSDOH) is the lead State agency for protecting the health and safety of people; providing credible information, assistance and resources to enhance health decisions and emergency response operations through strong partnerships, with other state agencies and local governments.

An act of terrorism, or a large scale natural disaster, targeting the New York State (NYS) population will require rapid access to large quantities of pharmaceuticals and medical

supplies. Such quantities may not be readily available unless special stockpiles are available. No one can anticipate exactly where a terrorist will strike and few state or local governments have the resources to create sufficient stockpiles on their own. Therefore, a national stockpile has been created as a resource for all.

In 1999 Congress charged the Department of Health and Human Services (DHHS) and the CDC with the establishment of the National Pharmaceutical Stockpile (NPS). The mission was to provide a re-supply of large quantities of essential medical material to states and communities during an emergency within twelve hours (12) of the federal decision to deploy. This national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration, airway maintenance supplies, and medical/surgical items was designed to supplement and re-supply state and local public health agencies in the event of a national emergency anywhere and at anytime within the U.S. or its territories.

In 2002 Congress renamed the NPS the *Strategic National Stockpile* (SNS), and moved the program under the Department of Homeland Security (DHS). It is now known as the Division of the Strategic National Stockpile (DSNS). The DSNS works with governmental and non-governmental partners to upgrade the nation's public health capacity to respond to a national emergency. Critical to the success of this initiative is ensuring capacities are developed at federal, state, and local levels to receive, stage, and dispense DSNS assets.

2.3 *CHEMPACK Pilot Project* While the DSNS Program is expected to respond within 12 hours, federal officials recognize that this response time will not be adequate for nerve agent events due to the need to provide timely medical intervention.

3.0 Hazard Analysis

3.1 *Background* Evidence of chemical weapons use in warfare has existed for over two millennia. In the Middle and Far East City-States they used burning sulphur and noxious smoke on enemy troops. At the end of the nineteenth century the rise of the modern chemical industry allowed for large-scale quantities of chemical weapons to become a reality[1]. Terrorists' attacks aimed at United States citizens and interests around the world culminated in the destruction of the World Trade Center and damage to the Pentagon on September 11, 2001.

The U.S government realized that terrorist groups were motivated, organized, funded and had the intent to further their goals by causing massive loss of life to U.S. citizens. Intelligence sources believe that these groups will not be content to continue using only conventional explosives and means to damage the United States' infrastructure and citizens. Due to the availability of chemical weapons, terrorist organizations may be able to obtain and deploy chemical weapons to create a weapon of mass destruction (WMD) event. These chemicals are commonly referred to as choking, blister, blood and nerve agents.

To respond to these threats, planners and responders must be able to quickly mobilize resources to minimize and neutralize the effect of an attack, or large scale exposure, involving chemical agents. In the aftermath of a WMD chemical event, or any other large-

scale exposure, the focus will be on response activities designed to mitigate loss of life and the destruction of property.

The CHEMPACK Project was initially developed to provide effective response to large scale nerve agent release resulting in many casualties. In March of 2012 the CDC released updated CHEMPACK Project guidance that allowed for the opening of a container to save life regardless of the number of casualties. In doing so the CDC recognized a nerve agent or organophosphate release may not result in a mass casualty event. However, any exposure to such agents may require antidotes that are not readily available to healthcare responders.

The updated guidance reiterates the five (5) principles of CHEMPACK deployment:

1. The removal of material is for a life-saving measure.
2. An alternative means of procurement is not available in a timely manner to support a medical emergency.
3. Product removed and used from CHEMPACK cache cannot be charged to patient.
4. Product removed by the case(s) only. Any unused portion of product will not be returned to CHEMPACK container.
5. There is no guarantee for immediate product replacement from the CDC

Note: Once a CHEMPACK container is opened, the program does not guarantee immediate product replacement. Project areas should continue to adhere to agreed procedures when opening a CHEMPACK container. Once a container door is breached, CHEMPACK points of contact should expect a call from CHEMPACK staff to inquire about the security of the container and the purpose and disposition of the deployed product.

3.2 Time *Sensitive Medical Intervention* Injuries sustained from nerve agent or organophosphate exposures require immediate medical intervention. They require specialized antidotes, which are frequently not available. Hazardous in both a liquid and vapor state, nerve agents or organophosphates can cause convulsions and death within minutes of exposure. Mitigation of casualties requires that medical personnel have effective antidotes accessible for medical intervention.

3.3 *How Nerve Agents Work* Acetylcholine is a neurotransmitter found in the central and peripheral nervous system where it acts to control muscular contraction(s). An enzyme called acetylcholine esterase stops the action of acetylcholine. Research in Germany in the late 1930's into insecticides lead to the discovery of a class of highly toxic chemicals which block the action of the enzyme acetylcholine esterase, causing muscle contractions to continue; both the central and peripheral nervous systems are affected.

Nerve agents are usually found in a liquid state, and have little or no smell. They can enter the body either through inhalation (vapor or aerosol) or through the skin and eyes (liquid droplets).

See table 2.4 below for general symptoms of nerve agent poisoning.

Symptoms of Nerve Agent Poisoning **2.4 Table 01**

Central Nervous System	Respiratory System	Cardiovascular System	Skeletal Muscles	Eyes (Ocular)
Irritability Nervousness Fatigue Memory Loss Slurred speech Unconsciousness Seizures Apnea Coma Death	Runny nose Bronchial secretions (Airways/Lungs) Chest tightness Difficulty breathing Respiratory Failure Death	Slowed heart rate High blood pressure Heart failure Death	Twitching Flaccid Paralysis	Pinpoint pupils Blurred vision Dim vision Eye pain Inflammation ATSDR

3.4 *Vulnerability* The release of nerve agents pose a significant health threat to the general population, especially if released in a heavily populated or enclosed area. These include but are not limited to:

- Government offices
- Foreign Consulates
- Transit Systems
- High Profile Events
- Landmarks
- Large Gatherings

4.0 Impact on Medical Security of the Community

4.1 *Health & Medical* Based on the location, population, type of agent, and the method of release, the right mixture of agent and atmospheric conditions will result in numerous casualties or fatalities. The resulting mass casualties may overwhelm both the pre-hospital and hospital healthcare system. Medical strategies focus on the use of antidotes that can reduce the effects of excess acetylcholine. Nerve agent antidotes include:

- Atropine sulfate, which blocks the effects of excess acetylcholine at its site of action.\

- Pralidoxime chloride (2-PAM), which reactivates the acetylcholine esterase and therefore reduces the levels of acetylcholine.\

- Diazepam, which reduces the severity of acetylcholine induced convulsions, which can cause long-term mental effects. Children, the elderly and the infirm are especially susceptible to low-level exposure. Responders must be able to quickly decontaminate and treat casualties. With advanced planning, training

and resources, mass casualty situations can be managed and morbidity reduced

- If present, chemical intoxication complicates the therapy for other underlying medical conditions (i.e. blast/burn victims). Additionally, actual casualties and the 'worried well' can quickly overwhelm the local healthcare system

5.0 CHEMPACK Formulary

The DSNS Program formulary requirements represent treatment capacity for 100 or 10,000 adults, using a variety of information sources and models, specifically:

- *The Joint Readiness Clinical Advisory Board (JRCAB)* for military services. The mission of JRCAB includes standardizing medical material and providing clinical, technical, and logistical expertise to ensure quality medical material is available to the armed services.
- *The Casualty and Resource Estimation Support Tool for Nuclear, Biological and Chemical Weapons (NBC CREST);* developed by the Center for Research and Education on Strategy and Technology; The US CREST Organization.
- *Clinical Experience* of CDC science and medical personnel.
- *Tokyo 'Sarin' Attack, 1995* A large scale, sarin poisoning, occurring in a Tokyo subway, with approximately 6,000 total patients treated by area hospitals. This incident provided valuable information on medical treatment or dosing requirements and emergency staging operations in large urban areas. Among the lessons learned: 65% of patients were self-referred to 17 area hospitals; not receiving initial EMS treatment prior to their arrival at the hospital. ***See Appendix B for additional formulary information.***

The CHEMPACK formulary assumes that 30% of the casualties have a mild nerve agent exposure, 40% a moderate exposure and 30% a severe exposure.

The current CHEMPACK formulary:

EMS Formulary Requirement **Table 01**

Resource	Mild 30%	Moderate 40%	Severe 30%	Total for 454 Patients
Mark 1 Kits				1200
Atropine Sulfate 0.4 mg/ml 20 ml	0			100
Diazepam 5 mg/ml auto-injector	0			300
Pralidoxime 1 gm inj 20ml	0			276
Diazepam 5 mg/ml vial, 10ml vial	0			50

Sterile Water for Injection (SWFI)				200
Atropen 0.5mg				12
Atropen 1.0mg				12

Hospital Formulary Requirement **Table 02**

Resource	Mild 30%	Moderate 40%	Severe 30%	Total for 1000 Patients
Mark 1 Kits	7	18	14	390
Atropine Sulfate 0.4mg/ml 20ml	10	40	35	850
Diazepam 5mg/ml auto-injector	0	1	7	80
Pralidoxime 1gm inj 20ml	14	148	111	2730
Diazepam 5mg/ml vial, 10ml	0	4	60	640
Sterile Water for Injection (SWFI)				2800
Atropen 0.5mg				144
Atropen 1.0mg				144

6.0 Shelf Life Extension Program (SLEP)

Sustainment costs for antidote material are considerably less for the DSNS Program than state and local governments through the use of the *Shelf Life Extension Program* or SLEP. This federal program was originally developed for the Department of Defense (DoD), by the Food and Drug Administration (FDA). It allows extension of the shelf life or expiration date for selected pharmaceuticals, under FDA guidelines. By using SLEP, the DSNS Program has a potential to save approximately $96 million dollars through cost avoidance, over a ten (10) year period. Participation in the SLEP program offers considerable savings over time through cost avoidance, and as such is the corner stone of the CHEMPACK Project. Requirements for participation in SLEP are:

6.1 *Ownership of Material* Pharmaceutical supplies must be owned by an agency of the federal government. For CHEMPACK it is the Center for Disease Control and Prevention (CDC).

6.2 *Temperature Requirements* Pharmaceuticals must be continuously monitored to ensure compliance with FDA temperature requirements.

6.3 *Environmental Requirements* Pharmaceuticals must not be exposed to any adverse environmental conditions. Cache locations must not have rodents, vermin or other environmental conditions conducive to poor sanitary conditions.

6.4 *Certification* DSNS Program must provide documentation to the FDA that the pharmaceuticals were stored and maintained continuously within set temperature ranges.

6.5 *Testing & Analysis* The DSNS program will retain samples from each pharmaceutical lot shipped to Project Areas and will review these lots monthly. When a lot is within ninety (90) days from expiration, the DSNS Program will have samples tested and analyzed. The FDA will check the results of this analysis to verify the efficacy of the product and determine if the shelf of that pharmaceutical can be extended and for how long.

6.6 *Re-labeling* The FDA can authorize an extension of shelf life and expiration dates of pharmaceuticals. Lots extended through SLEP will be relabeled, indicating the new expiration date. The DSNS Program will be responsible for re-labeling and repackaging material for the States and/or BT Project Areas. Additionally, the program will ensure pharmaceuticals in the CHEMPACK containers are maintained in a ready-to-use state.

7.0 Concept of CHEMPACK Deployment

The CHEMPACK Project is designed to provide NYS a sustainable, supplemental source of nerve agent antidotes that are available to sustain life following a nerve agent or organophosphate exposure. Selection of storage locations for CHEMPACK material is the responsibility of the State.

7.1 *Assumptions*

- A deliberate or accidental nerve agent or organophosphate release can occur anywhere.
- Any major release will require additional supplies of nerve agent antidotes.
- Antidotes are often in short supply locally
- The 'forward' placement of CHEMPACK assets in various locations (caches) throughout the State will expedite delivery of additional antidotes to locations that require them in the event of an emergency involving the exposure to a nerve agent or organophosphate material.

8.0 CHEMPACK Container Configurations

There are two (2) configurations for the CHEMPACK container. The container is wheeled and weighs between 500 to 700 lbs. The dimensions are 64.5" High 43"Wide 60.7"Long (Satco B) or 60.5 High 32.5 Wide 60.5 Long (Satco C). It has Lexan® Plexiglas walls, lined with a hardened wire mesh, to conform to FDA and the Drug Enforcement Agency (DEA) storage requirements for schedule IV controlled substances.

8.1 *EMS Containers* Designed for emergency responders, with the antidotes primarily packaged in single use auto-injectors. A percentage of the doses, based on population, are designed for pediatric patients. See ***Appendix B*** for additional formulary information.

EMS CHEMPACK Container for 454 Casualties			
	QTY	**Unit Pack**	**Cases**
Mark 1 auto-injector	1200	240	5
Atropine Sulfate 0.4mg/ml 20ml	100	100	1
Pralidoxime 1gm inj 20ml	276	276	1
Atropen 0.5 mg	144	144	1
Atropen 1.0 mg	144	144	1
Diazepam 5mg/ml auto-injector	300	150	2
Diazepam 5mg/ml vial, 10ml	50	50	1
Sterile water for injection (SWFI) 20cc Vials	200	100	2
Sensaphone® 2050	1	1	1

8.2 *Hospital Containers* Designed for hospital use, these nerve agent antidotes are primarily packaged in multiuse vials, allowing medical professionals to control the dosage as necessary for follow-up and long term care, and improve precise dosing. See ***Appendix B*** for additional formulary information.

Hospital CHEMPACK Container for 1000 Casualties			
	QTY	**Unit Pack**	**Cases**
Mark 1 auto-injector	480	240	2
Atropine Sulfate 0.4mg/ml 20ml	900	100	9
Pralidoxime 1gm inj 20ml	2760	276	10
Atropen 0.5 mg	144	12	12
Atropen 1.0 mg	144	12	12
Diazepam 5mg/ml auto-injector	150	150	1
Diazepam 5mg/ml vial, 10ml	650	50	13
Sterile water for injection (SWFI) 20cc Vials	2300	100	23
Sensaphone® 2050	1	1	1

9.0 Planning Considerations

9.1 *Incident Response* Counties must incorporate CHEMPACK assets into their existing Comprehensive Emergency Management Plan (CEMP). The responsibilities and coordination between Emergency Management, Emergency Medical Service, Hospitals, and local health departments, as well as other local and county responders and agencies, must be carefully developed. Communication trees and responsibilities must be clear and well defined. Communications issues, either the lack of information, or too much information to inappropriate agencies are principal reasons for delayed and inefficient response activities. County response plans should also consider the mechanisms for coordinating the acquisition of CHEMPACK assets in cases where the hub/spoke hospital is in a neighboring county.

9.2 *CHEMPACK Containers May be Moved Preemptively* NYS may temporarily move CHEMPACK containers for high profile or other special events, where large crowds are present and the normal placement of CHEMPACK supplies may not be adequate. However, environmental conditions of the CHEMPACK containers must be maintained at all times; special cargo transport trucks must be used. The costs of moving the containers will be the responsibility of the State. All moves must be coordinated with the CDC DSNS Logistics Section. They will provide technical assistance and specific information and requirements for staging the containers. NYS has CHEMPACK containers designated for this contingency and will not move containers currently located at storage sites within the counties.

9.3 *Mutual Aid Agreements* CHEMPACK may be used for mutual aid. In the event of an emergency, NYS may be requested to provide mutual aid to surrounding states and/or border countries, especially if there is knowledge of the availability of CHEMPACK assets. Careful consideration and modification of existing mutual agreements may be necessary. (See attachment J Cross Border Agreement) Similarly, in their planning efforts counties should consider the request and acquisition of additional CHEMPACK asset from the State (primary) and other counties (secondary) when the locally staged assets are exhausted.

9.4 *Coordination with Cache Locations* Early coordination with Cache locations, when possible, may greatly assist emergency operations by having key personnel on stand-by. Examples include:

- Coordinating efforts with law enforcement to allow for the expedited transfer of product from hub to spoke hospital or hub to incident scene.

- Clear release and distribution procedures. Cache storage locations (Hub Hospitals) need to understand who has custody of the key for the CHEMPACK container; who can authorize use; and what are the required forms to ensure proper accountability and control of CHEMPACK assets. **See *Appendix H* for CHEMPACK opening procedures.**

- Clear lines of communication and coordination. Cache storage locations need to ensure the proper coordination between the hub and spoke hospitals, and the required coordination points with county agencies (i.e., LHD, Law Enforcement, EMS, Emergency Management) to facilitate the rapid deployment of CHEMPACK assets between hospitals and incident sites.

9.5 *Transfer (Delivery) of CHEMPACK Material for Emergency Response* Depending on cache locations, transfer procedures will have to be developed to deliver CHEMPACK assets to emergency locations. Couriers from various agencies may be used to deliver `CHEMPACK supplies to an emergency scene and/or hospital and return to cache locations. Couriers may be designated from law enforcement, fire, and emergency medical responders as appropriate. Depending on the location and type of transfer, security issues and cross-county issues may have to be addressed.

9.6 *Custody Transfer* All CHEMPACK Plans should include the methodology to transfer CHEMPACK assets from storage locations to emergency scenes or hospitals. Authorized personnel to transport CHEMPACK material may be anyone having official duties for emergency response operations, and authorized by persons in charge of a given scene. A chain of custody for CHEMPACK material must be documented. A *Controlled Substance Custody Transfer Form* has been developed and should be used to record the transfer of material from a storage location to either an emergency scene or a hospital. This form is simple, in order to expedite the delivery of assets to an emergency scene. Hospital supplies should be delivered directly to a doctor and/or a licensed pharmacist, and their signature recorded. Emergency Scene assets should be delivered to the person in charge of the scene. See ***Attachment F-2*** for an example of the ***Controlled Substance Custody Transfer Form***.

9.7 *Return of CHEMPACK Material to Cache Locations* A simple checklist has been developed to document the amount of CHEMPACK material returned to a cache location and the amount of supplies used. This information must be reported to the

DSNS Program after an emergency. See ***Attachment F-3*** for an example of the ***Expenditure Form***.

9.8 *Additional Material Requirements* Additional materials are required to administer injectable drugs. The following is recommended to be on hand to begin treatment of patients (based on 1000 patients per Hospital CHEMPACK and 454 patients per EMS CHEMPACK):

SUPPLY ITEM	HOSPITAL CHEMPACK	EMS CHEMPACK
Saline Mini-bag 100cc (0.9% 100ml IV Piggyback mix)	384	384
IV Start Kits	200	400
IV Catheter, 20 gauge, 1 ¼" or equivalent	400	0
IV Catheter, 18 gauge, 1 ¼" or equivalent	0	800
Safety Glide 10cc 22 gauge X 1 ½" (syringe and needle) or equivalent	800	400
IV Administration Set, micro Drip 60 GTTS non-vented	384	400

10.0 Responsibilities of Division of Strategic National Stockpile Program

DSNS Program staff will manage the CHEMPACK Project and provide CHEMPACK material to NYS. Specifically the DSNS will:

10.1 *Procure CHEMPACK Material* DSNS Program staff will purchase and ship all CHEMPACK material and supplies to approved cache locations.

10.2 *Installation and Set-up* DSNS Program personnel will install CHEMPACK containers in each cache location, and set-up a Sensaphone®.

10.3 *Sensaphone®* CHEMPACK containers come equipped with a Sensaphone® 2050 monitoring device installed and maintained by the Centers for Disease Control and Prevention (CDC). The CDC Sensaphone® continuously monitors the containers for intrusion, environmental conditions (temperature), and electrical power. The Sensaphone® will notify (call) CHEMPACK Project personnel if problems are detected. The Sensaphone® validates the environmental storage of CHEMPACK supplies and is not to take the place of appropriate security to be provided by the

States or BT Project Areas. Future upgrades to the CHEMPACK containers will include replacement of the Sensaphone with a Temperature and Security Monitoring Device that is web based.

10.4 *Transfer Custody of Material* DSNS will transfer custody of CHEMPACK assets to the State designated agent, but retain ownership of all CHEMPACK assets.

10.5 *SLEP* maintain appropriate documentation of environmental conditions for eligible CHEMPACK material, and request FDA approval for shelf life extensions where appropriate. The DSNS Program will re-label SLEP extended material or replace stocks as necessary.

10.6 *Conduct Quality Assurance Inspections of Storage Locations* Prearranged, periodic, quality assurance inspections will be conducted at CHEMPACK cache locations. Inspections will be coordinated with local facility personnel throughout the life of the project.

10.7 *Assist with Emergency Operations or Logistics as Requested* The DSNS Program has extensive experience in moving and maintaining pharmaceuticals. The DSNS Program will assist with logistics and other special situations as required. This may be especially useful should NYS decide to temporarily preposition CHEMPACK containers, for special events or situations.

11.0 Responsibilities of New York State Department of Health

11.1 *Memoranda of Agreement* NYS must execute a signed MOA with the DSNS Program, agreeing to store, maintain and use their CHEMPACK supplies according to the specifications set by the CHEMPACK project. See ***Appendix A***

11.2 *Custody of Material* Custody of material will be transferred to NYS for their safeguard, storage and use in emergency operations. However, *the DSNS Program will retain ownership of CHEMPACK material.*

11.3 *NYSDOH CHEMPACK Program Contacts* In the event of a CHEMPACK alert, the storage location (hub hospital) will be contacted by one of the following CHEMPACK team members. CHEMPACK team members can also be contacted for any non-emergency issues or questions. Team members can be reached at the numbers below.

On-Call CHEMPACK POC	Office	Cell
Mr. Ralph Iler	518 474-2893	518 857-5592
Mr. Patrick Russell	518 474-2893	518 470-6653
Mr. Jeff Ballard	518 474-2893	518 860-0243
Mr. Dan Bedard	5184-2893	518 813-7480

11.4 *Identification of CHEMPACK Storage Site Locations* NYSDOH is responsible for the placement of CHEMPACK assets throughout the state. Seventy-two (72) acute care hospital facilities (outside of NYC) have been chosen based on geographical location and drive time analysis. NYSDOH also maintains four (4) containers in the Medical Emergency Response Cache (MERC), the state's stockpile of medical countermeasures (MCM), durable medical equipment and supplies.

11.5 *CHEMPACK Distribution Concept of Operations* CHEMPACK containers are configured to treat 1000 patients (Hospital Container) or 454 patients (EMS Container), amounts well beyond the ED surge capacity of any NYS Hospital.

- Dividing a Hospital container's assets into 4 (or 5) **partitions** marked Red, Yellow, Blue, Green (and Orange) is a NYSDOH planning strategy that allows any emergency responder to quickly identify and remove predetermined quantities of antidotes and deliver them to any designated hospital Emergency Department or scene of release. In this way one central storage location (Hub) will support several (Spoke) hospitals in close proximity. ***This is known as the hub-and-spoke concept****.* A distribution key or legend, explaining the labeling will be posted on the door of the container.

    - Partitions labeled RED indicate a Hub Hospital partition
    - Partitions labeled GREEN indicate an EMS partition, a Spoke Hospital partition, or additional Hub Hospital partition
    - Partitions labeled BLUE or YELLOW indicate a Spoke Hospital partition or additional Hub Hospital partition
    - Partitions labeled ORANGE indicate EMS or Hospital partition

- With the exception of the ATROPEN 0.5mg and 1.0mg auto injectors no boxes/cases will have to be opened prior to distribution. Due to the packaging of the ATROPENs, those boxes will have to be opened when the CHEMPACK container is opened. **All boxes to be opened when the container is opened are marked "Open and Distribute" with appropriate color coded labels affixed to the outside of the box.**

- Color coding expedites selection and distribution. When a color coded partition is picked from a container to be shipped, staff at the hub storage site does not have to inventory all of the boxes in the container. They can locate all boxes labeled with the color chosen, put them on a cart, and take them to the point of pick up for transport (or deliver to the ED) as indicated in the hospital's CHEMPACK plan.

11.6 *Correct out of Compliance Conditions for Caches* NYS and storage sites will apply resources and assets to correct non-complying environmental and security conditions in a timely manner, normally within two (2) hours**. However, it is critical that the temperature NEVER exceed 86 degrees, so response time may be less than two (2) hours.** *When conditions cannot be corrected within 12 hours, they must coordinate with the DSNS Program point of contact for movement of the CHEMPACK container(s) to an acceptable location, or other corrective actions to be determined on a case-by-case basis, to protect the quality or security of the material*. Response protocols are located in ***Appendix F***.

11.7 *Develop Integrated Emergency Response Procedures* NYS and Counties must modify their existing CEMP to incorporate CHEMPACK material into their response procedures.

11.8 *Replacement Requests* Currently the CHEMPACK Project is not funded to replace CHEMPACK assets used for an emergency event. However, requests for replenishment of CHEMPACK assets should be made to the DSNS Program as soon as possible after their use. Replacement requests will be the responsibility of NYS. The DSNS Program will attempt to secure federal funding to replace and restock supplies used in response to an emergency event.

12.0 Responsibilities for Cache Storage Locations (Hub Hospitals)

Cache storage locations must be of a suitable size, designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, and security conditions for storage of pharmaceuticals. See reference ii for specific environmental references and standards. Specifically cache storage locations must meet the following:

12.1 *DEA Registered License* A signature is required from pharmacy or medical professional with a DEA registration for the transfer of controlled substances. We recommend that a DEA site license be used, where possible, instead of individual registrant licenses. If individual licenses are used a method or procedure must be implemented to ensure notification of DSNS Program when there is a change of custody, facility personnel or type of license. Practitioner registrations are not approved for use in the CHEMPACK program.

12.2 *Storage Space* Each cache location must have a minimum of 50 square feet *per container (Satco B)* or 40 square feet *per container (Satco C).*

12.3 *Accessibility* Cache locations must be accessible to 20’ or larger trucks, and emergency responders and their vehicles. A loading dock, ramp, or forklift may be required for most locations, and the distance between the loading dock and the actual Cache storage room must be reasonable. The containers are on wheels, but are very

heavy and can weigh between 500 and 700 pounds. A freight elevator may be necessary in some locations.

12.4 *Mobility Cache locations* must have 72" aisles and doorways of suitable width for movement of CHEMPACK containers. Be aware that carpets and other floor coverings may impede movement of the CHEMPACK containers.

12.5 *Temperature/Environmental requirements* Room temperature must be continuously maintained between 68° and 77° Fahrenheit. A thermostat lock or other system preventing the altering of temperature is recommended. The room must be designed to prevent the entry of rodents and/or vermin into the storage area. Humidity must be maintained below 60% to prevent visible mold growth. Storage locations should have standard procedures regarding eating, drinking and smoking to prevent unsanitary conditions from developing.

12.6 *Electrical Power* A standard 120VAC, 60Hz, 10W, UL-listed power supply is required for each Sensaphone®. The Sensaphone® is equipped with 12-hour battery back up. Additional back-up or emergency electrical power must be available for the Sensaphone® and should be of a type that begins automatically when power is interrupted and be able to maintain power for at least 12 hours. Potential cache locations equipped with back-up generators capable of maintaining temperature during a power outage are preferred, but an uninterrupted power source (UPS) may be minimally acceptable.

12.7 *Phone Lines* Cache locations must have one (1) *analog* phone line for each Sensaphone® (analog phone lines are the type used for fax machines). This phone line must be a Plain Old Telephone System (POTS) line. POTS line requirements will be discontinued when the *Sensaphone* monitoring device is replaced.

12.8 *Fire Suppression* A fire suppression system is required for cache storage locations. Automatic sprinklers are recommended but not required.

12.9 *Monitoring* Cache locations must be physically checked monthly for continued compliance with all the above requirements. Storage sites must complete a monthly Quality Assurance Assessment Survey located on the Health Emergency Response Data System (HERDS). Surveys can only be completed during the current month and should be submitted by the fifth day of each month. ***See Attachment F-1***

12.10 *Environmental Response* Personnel must be available to respond to emergency environmental alarms or conditions, within one hour from notification. Current contact information, for all cache locations, must be provided to NYSDOH CHEMPACK Project personnel prior to the installation of the containers. The NYSDOH CHEMPACK Project personnel must be notified within seven (7) days of any changes in contact personnel.

12.11 *Security CHEMPACK* containers have a Schedule IV controlled substance, Diazepam, which must be secured according to DEA, FDA, and state or local pharmaceutical regulations. In addition, 24 hour monitoring and controlled access must be provided for CHEMPACK assets. Pilferage and unauthorized access to pharmaceuticals is illegal and may substantially increase cost of the CHEMPACK stockpile and potentially negate its utility.

The building, or at least the CHEMPACK storage room itself must have controlled access. Additionally, cache locations must have:

- *Alarms and Monitoring* A security system is required for cache locations not physically having continuous monitoring (24 hours a day, 7 days a week). Motion detectors, contact sensors or other types of security systems may be used, but the system must be monitored at all times (24 hours a day, 7 days a week) and have notification abilities to contact designated responders should someone attempt to break into a cache location.

- *Security Response* Cache locations must have staff designated, who will respond to any security alarm within 15 minutes. NYSDOH must have current security contact information for all cache locations.

- *Notification of Container Opening* Cache locations must establish notification protocols in their CHEMPACK Plan. Responsibility for notifications should not be assigned to personnel directly involved in the CHEMPACK opening and distribution process. Responsibility for notifications should be delegated and performed as soon as the contained is accessed. At a minimum, notification must be made to the County Health Department and the County Office of Emergency Management. The containers are equipped with a CDC Sensaphone monitoring device. The DSNS program will receive an alarm when a container is opened prompting notification to NYSDOH.

12.12 *Storage Site Contacts* Each CHEMPACK Hub Hospital Single must identify a primary point of contact (POC) and an alternate for communication and coordination with NYSDOH. POC(s) are responsible for ensuring the CHEMPACK container(s) in their facility are stored in a secure environment with adequate climate control. POC(s) also assist NYSDOH and DSNS CHEMPACK staff during scheduled maintenance visits or Sensaphone alerts that require immediate attention.

12.13 *Container Sustainment* All product in the CHEMPACK container is in SLEP (refer to Section 5.6). Staff from the CDC/SNS CHEMPACK project is responsible for removal of product as it approaches its labeled expiration dating and replacing the same with current product. Storage site contacts and a facility pharmacist need to be present during the sustainment process.

13.0 Response - When is CHEMPACK Used?

The Shelf Life Extension Program is an essential part of CHEMPACK. NYS and Counties must agree to break the container seal and use assets **only when it is determined that an accidental or intentional nerve agent release has threatened the medical security of the community, is beyond local emergency response capabilities and is medically necessary to save life.** Once a CHEMPACK container is opened, contents may no longer be eligible for SLEP.

13.1 *Hub Hospital*

- Surge of patients exhausts antidote supply
- Emergency Department physician requests to open CHEMPACK
- Open container and distribute a partition(s)
- Hospital activates Hospital Incident Command System (HICS)
- Notify County Office of Emergency Management (OEM) & New York State Department of Health (DOH) Regional Office Administrator on Duty (AOD)
- Sign custody forms
- County OEM activates county response plan

13.2 *Spoke Hospital*

- Surge of patients exhausts antidote supply
- ED physician of spoke hospital requests CHEMPACK assets
  - Or
- County Office of Emergency Management requests CHEMPACK assets
- Hospital activates Hospital Incident Command System (HICS)
- Notify County Office of Emergency Management (OEM) & New York State Department of Health (DOH) Regional Office Administrator on Duty (AOD)
- Sign custody forms
- OEM activates county response plan

13.3 *Who has authorization to direct CHEMPACK container opening*

- Attending Physician of Emergency Department
- HUB and/or Spoke Hospital
- County Emergency Management
- County Health Department Commissioner/Director
- New York State Department of Health
- Centers for Disease Control
- County Executive / or Chairperson of County Legislature

13.4 *For what purpose should CHEMPACK assets be considered*

- Medical Decision to Activate
- Nerve agent antidote needed to save life
- Antidote need is beyond local supplies
- Not meant as a “First Response” asset
- Not for prophylaxis or pre-treatment

14.0 Training

Any response agency that plays a role in the CHEMPACK response or utilization of CHEMPACK assets has an obligation to participate in planning and conduct inter - agency training.

- Hospital personnel – Pharmacy, Administrative and Emergency Department Staff
- Local Public Health Departments
- Local Office of Emergency Management
- Law Enforcement
- Regional EMS Directors
- County EMS and Fire Coordinators
- Local Fire and EMS Agencies

14.1 *Goals and objectives of training*

- Review current CHEMPACK procedures and updates designed to improve the process.
- Improve communication and knowledge in the CHEMPACK program.

- Describe and understand the mission statement and intent of the CHEMPACK program.
- Understand the need for rapid access to nerve agent antidotes.

- Describe how the CHEMPACK fits into the overall SNS program and the local, state and federal response to a public health crisis involving a nerve agent release.

- Understand individual responsibilities and learn how they relate to the larger organizational and community response planning.

- Comprehend and apply CHEMPACK protocols found in the NYS CHEMPACK Guidelines Handbook to local response planning.

- Identify the extent and need of individual organizations to support the use of CHEMPACK assets

- Apply creative problem solving and flexible thinking to unusual challenges within their functional responsibilities and evaluate effectiveness of actions taken.

15.0 Post Incident

Incident documentation should begin as soon as possible following emergency operations involving CHEMPACK assets. Details that are initially clear in emergency responder's memory will fade rapidly after the incident.

15.1 *Documentation* NYS and Counties must document and maintain a historical record of emergency operations involving CHEMPACK material.

15.2 DSNS Notification The DSNS Program shall be notified of any instance when a CHEMPACK container is opened, or the seal compromised.

15.3 *Replacement Requests* Currently the CHEMPACK Project is not funded to replace CHEMPACK assets used for an emergency event. However, requests for

replenishment of CHEMPACK assets should be made to the DSNS Program as soon as possible after their use. Replacement requests will be the responsibility of NYS. The DSNS Program will attempt to secure federal funding to replace and restock supplies used in response to an emergency event

16.0 Training Containers

Emergency response operations require frequent, interagency training exercises for cohesive and effective response. State and local agencies should incorporate CHEMPACK into nerve agent emergency response planning, training and exercises.

Hospital and EMS CHEMPACK training containers are available for use during training and exercises. Training containers will be filled with boxes that replicate the size of the actual CHEMPACK containers. NYSDOH will arrange for the delivery and retrieval of the containers. See ***Attachment F-4*** for additional Information on training containers.

17.0 Special Event Cache Containers

NYS has established a cache of two (2) EMS-type and two (2) Hospital-type CHEMPACK containers for high profile or other special events where large crowds of people attending special events may present a higher danger of chemical attack and the normal placement of CHEMPACK supplies may not be adequate. These high profile or special events are not regular events such as football games, concerts, etc, but events of national or international significance. The CHEMPACK containers may be moved from the storage location to special events if necessary. However, the established environmental conditions of the CHEMPACK containers must be maintained at all times. NYS must use special cargo transport vehicles with environmental systems and will pay for the movement of the CHEMPACK containers to support the special events. However, there are ancillary costs that will be the responsibility of the requesting agency, such as phone lines, door alarms, etc. All moves must be coordinated with the CDC CHEMPACK staff prior to execution. In case of multiple qualifying special events, the cache containers will be deployed on the basis of statewide priorities based on threat assessments. Request procedures for the Special Event Caches are found under a separate letter.

The State has established a policy for those requesting the Special Events CHEMPACK Containers. The policy includes a NYS CHEMPACK CACHE questionnaire designed for use by the requesting jurisdiction. See ***Appendix G*** for further information.

FORMS

NEW YORK STATE
CHEMPACK CACHE
MONTHLY QUALITY ASSESSMENT CHECKLIST

Site Name	
Region:	
Evaluator	
Date	**Time:**

The CHEMPACK Program will use this survey to evaluate CHEMPACK cache sites for maintenance of medical material storage guidelines, as defined in various reference documents.

The cache storage site representative will conduct monthly assessments at each CHEMPACK cache location area. NYS CHEMPACK Program requires the checklist each month by the **1st business day.**

The CHEMPACK Program intends this to be a "no blame" process. The goal of this process is to identify existing and potential material storage problems/risks, and will coordinate with the State to make improvements. All sections within this document cover those areas deemed essential for maintaining a high level of quality standards stated within the referenced documents.

Quality Assurance/Quality Control Assessment

Requirement	YES	NO	COMMENTS
Is proper monitoring of temperature being verified?	☐	☐	
Are sanitary conditions being maintained to prevent the product from being adulterated / compromised? (i.e. Entry points protected from vermin and humidity controlled to prevent visible mold growth)	☐	☐	
Are there adequate power/electrical capabilities?	☐	☐	
Will the facility allow for ease of inventorying, stock replenishment, and rapid mobilization?	☐	☐	
Is security access limited to designated staff?	☐	☐	
Are other products being stored in cache room or other processes taking place at the facility that could contaminate the medical material?	☐	☐	
Does the facility have adequate lighting, ventilation, and protection from water damage?	☐	☐	
Are eating, drinking and/or smoking prohibited in the immediate storage area?	☐	☐	
Are external security systems in place and operational?	☐	☐	
Are fire suppression systems and alarms maintained and operational?	☐	☐	
Verify that the DSNS Program seals have not been tampered with or any materials been removed from the CHEMPACK containers?	☐	☐	
Verify the packing lists are attached to the CHEMPACK containers?	☐	☐	
Have the containers been moved for forward deployed?	☐	☐	N/A: ☐ Comments:

References:
1. CFR21, Chapters 1& 2 April 2002
2. Gorman S. Factors Used by DEA to Evaluate Drug Storage Room Security March 24, 2000
3. VA Construction Standard CD-49. Physical Security Requirements and Options. Nov. 1991
4. Pharmacy Benefits Management strategic health Group. VHA Handbook 1108.1 Controlled Substances (Pharmacy Stock). May 16, 1997
5. Material Handlers Training Guide TG-90-1, Department of Veterans Affairs
6. Army Regulation 710-2 Inventory Management Supply Policy Below the Wholesale Level Chapter 2
7. Air Force Manual 23-110 Vol. 5 Air Force Medical Material Management System Chapter 19

Completion instructions on back of form

PART B- RECEIPT of CHEMPACK Material - To be completed by the Receiving Location

The following controlled substances have been delivered to:

(Location)_____(City)_____

Diazepam 5mg/ml (10ml) vials (50 vials per box) Number of Boxes_____

Diazepam 5mg/ml (2ml) auto-injector (150 auto-injectors per box) Number of Boxes_____

Non-controlled substances Number of Boxes_____

Name of Receiver (print)_____ Signature _____

Name of Transporter (print)_____Signature_____

Agency of Transporter (print) _____

Date _____ Time of delivery_____

Partition Color

Blue

Green

Orange

Red

White

Yellow

PART A- SHIPMENT of CHEMPACK Material - To be completed by the Hub Hospital

The following controlled substances have been removed from Drug Enforcement Administration (DEA) Registrant:

(Hospital Name):_____

for delivery to (Location)_____(City)_____

Diazepam 5mg/ml (10ml) vials (50 vials per box) Number of Boxes_____

Diazepam 5mg/ml (2ml) auto-injector (150 auto-injectors per box) Number of Boxes_____

Non-controlled substances Number of Boxes_____

Name of Transporter (print)_____ Signature _____

Agency of Transporter (print) _____

Name of Hospital Rep (print) _____ Signature_____

Title of Hospital Rep (print) _____

Date _____ Time of delivery_____

Partition Color

Blue

Green

Orange

Red

White

Yellow

White Copy to NYSDOH Health Emergency Preparedness Program Central Office (via Hub Hospital)
Yellow Copy to Hub Hospital
Pink Copy to Receiving Location

March 2008
Previous Editions Are Obsolete

The Hub Hospital completes Part A of this form.

1. Enter the Hub Hospital's name into Hospital Name line.
2. Enter either spoke hospital or field location (with City) in appropriate lines
3. Enter the number of boxes sent in the appropriate spaces
4. Circle the partition color that is being sent with this paperwork
5. Enter the name and agency of transporter (with signature)
6. Enter name and title of Hub Hospital representative (with signature)
7. Enter date and time of transfer
8. Tear off Part A of the Form.
   a. White and Yellow copies are maintained by the Hub Hospital
   b. Pink Copy is sent with transporter for the receiving location records

The Receiving Location completes Part B of this form.

1. Enter the receiving location with city into appropriate spaces
2. Enter the number of boxes received in the appropriate spaces
3. Circle the partition color received
4. Enter the name of the receiver (with signature)
5. Enter the name and agency of the transporter (with signature)
6. Enter date and time of delivery
7. Tear off Part B of the Form
   a. White and Yellow copies are sent back to Hub Hospital
   b. Pink Copy is maintained by the receiving location

Post-Incident

1. The Hub Hospital must return the White copies of Part A and B to the NYSDOH Health Emergency Preparedness Central office.
2. The Hub Hospital must retain the Yellow copies of Part A and B for their records.
3. The Receiving Location must maintain the Pink copies of Part A and B for their records.

The Hub Hospital completes Part A of this form.

9. Enter the Hub Hospital's name into Hospital Name line.
10. Enter either spoke hospital or field location (with City) in appropriate lines
11. Enter the number of boxes sent in the appropriate spaces
12. Circle the partition color that is being sent with this paperwork
13. Enter the name and agency of transporter (with signature)
14. Enter name and title of Hub Hospital representative (with signature)
15. Enter date and time of transfer
16. Tear off Part A of the Form.
    a. White and Yellow copies are maintained by the Hub Hospital
    b. Pink Copy is sent with transporter for the receiving location records

The Receiving Location completes Part B of this form.

8. Enter the receiving location with city into appropriate spaces
9. Enter the number of boxes received in the appropriate spaces
10. Circle the partition color received
11. Enter the name of the receiver (with signature)
12. Enter the name and agency of the transporter (with signature)
13. Enter date and time of delivery
14. Tear off Part B of the Form
    a. White and Yellow copies are sent back to Hub Hospital
    b. Pink Copy is maintained by the receiving location

Post-Incident

4. The Hub Hospital must return the White copies of Part A and B to the NYSDOH Health Emergency Preparedness Central office.
5. The Hub Hospital must retain the Yellow copies of Part A and B for their records.
6. The Receiving Location must maintain the Pink copies of Part A and B for their records.

EXPENDITURE ACCOUNTING FORM

Dispensing Organization_____

Dispensing Organization Type (i.e. H1, H2, E1 etc)_____

Date of Incident: _____

Individual Items **See back of form**	**Amount Received**	**Amount Distributed**	**Amount Returned**
Mark 1 auto-injector Kits			
Atropine Sulfate 0.4mg/ml 20 ml			
Pralidoxime 1gm inj 20 ml			
Diazepam 5mg/ml auto-injector			
Diazepam 5mg/ml vial 10 ml			
Sterile Water for Injection (SWFI)			
Atropen 0.5mg			
Atropen 1.0mg			

SEE REVERSE SIDE FOR INDIVIDUAL ITEM AMOUNTS PER BOX

INDIVIDUAL ITEM AMOUNTS

	1 box	2 boxes	3 boxes	4 boxes	5 boxes	6 boxes	7 boxes	8 boxes	12 boxes
Mark 1 autoinjector Kits	240	480	720	960	1200	1440	1680	1920	
Atropine Sulfate 0.4mg/ml 20 ml	100	200	300	400	500	600			
Pralidoxime 1gm inj 20 ml	276	552	828	1104	1380	1656			
Diazepam 5mg/ml autoinjector	150	300	450	600					
Diazepam 5mg/ml vial 10 ml	50	100	150	200	250	300	350	400	
Sterile Water for Injection (SWFI)	100	200	300	400	500	600	700	800	
Atropen 0.5mg	12	24	36						144
Atropen 1.0mg	12	24	36						144

NYS DOH CHEMPACK TRAINING CONTAINER REQUEST

[Fax this form to: 518 402-6228]

Current Date: _____ **Time:** _____

Requested Date(s): _____ **Time:** _____

Hub Hospital: _____

Street _____

City _____ **County** _____

Hospital CHEMPACK POC Making Request _____

Contact Phone Number _____

Contact E-Mail _____

Request is for a Hospital CHEMPACK (Option 1) Training Container ☐

Request is for a Hospital CHEMPACK (Option 2) Training Container ☐

Request is for an EMS CHEMPACK (Option 1) Training Container ☐

Request is for an EMS CHEMPACK (Option 2) Training Container ☐

List all state, county, local government agencies, health care facilities, and community groups participating in the exercise.

Agency	Point of Contact

CDC CHEMPACK Cache Storage Location Checklist

Date of survey:	**Name:**	**Phone:**
Name of facility:		
Cache address:		
Number of containers to be housed:		

STORAGE LOCATION REQUIREMENTS

ACCESSIBILITY	**Yes**	**No**	**Comments**
1. Is the cache location accessible to large trucks? (Must accommodate minimum 20 ft trailer and suitable turn around space)	☐	☐	
2. Is a loading dock or fork lift available?	☐	☐	
3. Distance of cache area from loading dock? ____ft.	☐	☐	
4. 72" aisles and 45" doorways in and out of the facility?	☐	☐	
5. Sloped hallways and/or ramps (weight > 1300 lbs)?	☐	☐	
6. Freight elevators available and can they accommodate container?	☐	☐	
7. Actual doorway(s) width(s):_____	☐	☐	
8. Actual aisle(s) width(s):_____	☐	☐	
9. Have alternate container movement routes been identified?	☐	☐	

Note: Make a movement diagram for CHEMPACK container(s), if only certain doors/aisles within a facility meet the requirements.

Actual container dimensions are: **64.5" High 43"Wide 60.7"Long (Satco B) or 60.5 High 32.5 Wide 60.5 Long (Satco C)**

SPACE	**Yes**	**No**	**Comments**
10. Minimum of 50 square feet per container?	☐	☐	
11. Actual room dimensions: *Width_____ft. x length____ft* = _____ sq ft.	☐	☐	
12. Total # Containers: _____ x 50 sq ft = _____ (required sq. ft.) *Note: See attached cache storage facility diagram*.	☐	☐	

ENVIRONMENTAL CONDITIONS	**Yes**	**No**	**Comments**
13. System to maintain temperature between 68° to 77° F	☐	☐	
14. Are humidity levels maintained below 60%?	☐	☐	
15. Is there a thermostat to regulate environmental conditions?	☐	☐	
16. Thermostat lock? (recommended, but not required)	☐	☐	
17. Are personnel designated to respond to correct room temperature deviations within one hour of Sensaphone alarm?	☐	☐	
18. Is there adequate lighting to ensure CHEMPACK personnel can clearly identify lot numbers and product expiration dates?	☐	☐	
19. Is the location free of solvents, petroleum products, and flammable materials?	☐	☐	

ENVIRONMENTAL CONDITIONS (continued)	Yes	No	Comments
20. Is the cache location clear of trash?	☐	☐	
21. Does the cache location have pest control?	☐	☐	

PHONE LINES	Yes	No	Comments
22. Is there one dedicated analog POTS phone line per Sensaphone?	☐	☐	
23. Total number of dedicated analog phone line (s) needed:_____			

ELECTRIC POWER	Yes	No	Comments
24. Is there one dedicated 120 VAC, 60 Hz power outlet with surge protection available per Sensaphone?	☐	☐	
25. Per Sensaphone specifications, is the unit located away from strong electro-static, electromagnetic, magnetic or radioactive fields? *For example*: *X-ray machine, MRI, etc*.	☐	☐	
26. Is back-up emergency power available? List Type *(Uninterruptible power supply (UPS) or existing facility emergency generator adequate)*	☐	☐	
27. Distance (unobstructed) between phone line & outlet?	☐	☐	
28. Total number of 120 VAC, 60 Hz outlet (s) needed: _____	☐	☐	

SECURITY and ALARM RESPONSE	Yes	No	Comments
29. Does the storage location have controlled access?	☐	☐	
30. Has a list of all personnel with access to the CHEMPACK containers been provided?	☐	☐	
31. Is access to keys limited and controlled?	☐	☐	
32. Is the key custodian the cache location pharmacy director or a designated representative?	☐	☐	
33. Is a security system or continuous surveillance available?	☐	☐	
34. What type of intrusion detection device is installed?	☐	☐	
a. Motion sensors?	☐	☐	
b. Security cameras? (Recommended, but not required)			
35. Do security or pharmacy personnel physically monitor the sensor on a 24-hour basis?	☐	☐	
36. Do the intrusion detection devices detect movement in and around the CHEMPACK containers?	☐	☐	
37. Are procedures in place to test sensors according to the manufacturer's specifications?	☐	☐	
38. Are there personnel assigned to respond within 15 minutes of a security alarm?	☐	☐	

FIRE SUPPRESSION	Yes	No	Comments
39. Is there a fire detection system present and functional?	☐	☐	
40. Is there a fire sprinkler system? (recommended, but not required) if so, what type?	☐	☐	
41. If not, what type of fire suppression system is in place?			

CONTACTS	Name	Phone	Cell Phone	Pager	Email

42. Facility Emergency Contacts:
    Primary:
    Alternate:

43. Security Emergency Contacts:
    Primary:
    Alternate:

44. Comments/recommendations (attach additional sheets as required):

I have been provided a copy of this checklist and recommendations.

Name and title of cache location POC: _____

Signature: _____ Date: _____

Name of Field Team Lead or Logistics Technician: _____

Signature: _____ Date: _____

APPENDIX A
MEMORANDUM OF AGREEMENT BETWEEN
THE CENTERS FOR DISEASE CONTROL AND PREVENTION,
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
AND
NEW YORK

I. PURPOSE

To effectively respond to public health emergencies, the Centers for Disease Control and Prevention ("CDC") agrees to pre-position CHEMPACK Assets in New York ("RECIPIENT"). The CDC and the RECIPIENT (collectively, the "parties") agree to the terms, conditions, and responsibilities contained in this Memorandum of Agreement ("MOA"). This MOA is independent of, and supplements, any agreement between CDC and RECIPIENT concerning the Strategic National Stockpile, but supersedes any previous agreements concerning CHEMPACK Assets.

II. DEFINITIONS

"Cache Location" means a facility of suitable size to store CHEMPACK Containers, designed to provide adequate lighting, ventilation, security, and climate control, of CHEMPACK Assets.

"CHEMPACK Assets" means assets listed in Appendix I.

"CHEMPACK Containers" means DEA-approved, self-monitoring, SATCO units containing the CHEMPACK Assets listed in Appendix I and equipped with a padlock, temperature and security monitoring device, and CHEMPACK-serial-numbered container seal.

III. RESPONSIBILITIES

A. Prior to receipt of CHEMPACK Containers and CHEMPACK Assets, RECIPIENT will develop and provide to CDC an operational plan for storage, maintenance, monitoring, deployment, use, and administration of CHEMPACK Assets, which will address asset placement, distribution, coverage areas, and security. As part of RECIPIENT's plan, or in another format approved by CDC, RECIPIENT will provide CDC the name, title/position, office phone number, cell phone number, pager number, e-mail address, and fax number for: (1) a primary and alternate state-wide point of contact and (2) a primary and alternate point of contact for each Cache Location. In addition, RECIPIENT will provide CDC with a list of all personnel, including name, title/position, primary phone number, and alternate phone number, who have access to CHEMPACK Containers and CHEMPACK Assets. RECIPIENT will notify CDC of any changes in the plan or personnel and will provide updated plan and contact information within one business day of the change. Upon receiving RECIPIENT's operational plan, CDC will, at its own cost, transport and deliver CHEMPACK Containers to a Cache Location identified by RECIPIENT and determined suitable by CDC.

B. Upon delivery, RECIPIENT will maintain CHEMPACK Containers as described in Appendix II. RECIPIENT will contact CDC as soon as possible after detecting any non-compliant condition but

no later than two hours after detecting a non-compliant deviation of climate control. RECIPIENT will begin to correct any non-compliant condition immediately upon discovery and, for any condition that cannot be corrected within 12 hours; RECIPIENT will coordinate with CDC to move affected CHEMPACK Containers to a mutually acceptable location. RECIPIENT will report any loss or compromise of Cache Locations, CHEMPACK Containers, or CHEMPACK Assets immediately upon discovery, and will report within 48 hours the circumstances resulting in the loss or compromise, the nature of the loss or compromise, and the types and amounts of any CHEMPACK Containers or Assets lost, compromised, or destroyed.

C. RECIPIENT will maintain the integrity of the CHEMPACK Container seal until authorized state or local officials determine that deployment to respond to a nerve agent release is warranted. RECIPIENT 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. RECIPIENT will notify CDC within 24-48 hours of a deployment and report the types and amounts of CHEMPACK Assets: (1) used in the deployment; and (2) remaining product in the CHEMPACK Container. CDC will reseal the container following a joint inventory conducted by CDC and the RECIPIENT.

D. RECIPIENT may temporarily transport CHEMPACK Containers for RECIPIENT- 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. RECIPIENT must notify CDC at least 48 hours prior to such movement;

   b. RECIPIENT's notification must be made telephonically or in writing to the designated CDC CHEMPACK Program Preparedness Branch program consultant AND the CHEMPACK Fielding Team Lead;

   c. RECIPIENT must maintain temperature and security requirements described in Appendix II of this MOA throughout transportation; and

   d. RECIPIENT assumes responsibility for all costs associated with transport of CHEMPACK Containers not specifically directed by the CHEMPACK Program.

E. Any movement of CHEMPACK Containers not described in paragraph III.D, above, must be approved by CDC.

F. Upon request from CDC, RECIPIENT will provide access to RECIPIENT’s Cache Location to allow CDC to perform:

   a. routine review of facilities holding CHEMPACK Assets and to inventory, restock, and remove expiring/expired CHEMPACK Assets; and

   b. periodic audits, including quality assurance and quality control inspections, to verify that the RECIPIENT is complying with the terms and conditions of this MOA.

G. CDC and RECIPIENT will jointly inventory CHEMPACK Containers approximately every 12 to 24 months or as required as determined by CDC.

H. RECIPIENT agrees to provide CHEMPACK Assets to patients free-of-charge.

IV. COSTS

Except where otherwise described in this MOA, each party is responsible for its own costs. CDC's responsibilities are subject to the availability of appropriated funds. CDC is generally not funded to replace CHEMPACK Assets and CHEMPACK Containers lost, compromised, or destroyed, but may replenish or replace, or assist RECIPIENT in identifying and/or paying for potential mechanisms to replenish or replace, CHEMPACK Assets used in response to a nerve agent incident or as a result of circumstances beyond the control of the parties, e.g., natural disasters.

V. OWNERSHIP

CDC retains ownership of all CHEMPACK Assets and CHEMPACK Containers, including after such Assets and Containers have been delivered to RECIPIENT and RECIPIENT has assumed custody.

VI. COMPLIANCE WITH US DRUG ENFORCEMENT AGENCY REQUIREMENTS

A. RECIPIENT agrees to comply with all applicable federal, state, and local requirements regarding storage, use, and handling of controlled substances, including, but not limited, those described in 21 CFR Parts 1301 and 1304.

B. RECIPIENT must designate a pharmaceutical or medical professional with a DEA-registration who will sign for and accept custody for CHEMPACK Assets and who will be responsible for ensuring compliance with the terms and conditions of this MOA including Appendix II.

C. RECIPIENT will ensure that each CHEMPACK cache site possesses a valid, separate DEA registration.

D. RECIPIENT will ensure that only the following DEA registrants assume custody of CHEMPACK controlled substances: Distributor, Hospital/Clinic, Emergency Medical Services and Retail Pharmacy. Practitioner registrations are not approved for use in the CHEMPACK program.

E. RECIPIENT must provide the DEA-registrant's contact information (name, license number, primary and alternate phone number) two weeks prior to CDC's schedule delivery of any CHEMPACK Assets. RECIPIENT will ensure that the DEA-registrant will be present for all CDC visits.

VII. REQUESTS FOR INFORMATION

Under 42 USC § 247d-6b, federal agencies are prohibited from disclosing under the Freedom of Information Act (5 USC § 552) any information identifying the location at which CHEMPACK Assets are stored. To the extent permitted by law, the parties agree that neither will disclose the nature of this effort or the terms of this MOA to any person or entity, except as may be necessary to fulfill their respective missions and statutory and regulatory responsibilities. The parties agree to notify one another before making any such disclosure.

VIII. LIABILITY

Each party to this MOA shall be responsible for its own acts and omissions and those of its officers, employees, and agents. No party to this MOA shall be responsible for the acts or omissions of entities not a party to this MOA. Neither party to this MOA agrees to release, hold harmless, or indemnify the other party from liability that may arise or relate to this MOA.

IX. NO PRIVATE RIGHT CREATED

This document is an internal MOA between the parties and does not create or confer any right or benefit on any other person or party, private or public. Nothing in this MOA is intended to restrict the authority of either signatory to act as provided by law or regulation, or to restrict any agency from enforcing any laws within its authority or jurisdiction.

X. SETTLEMENT OF DISPUTES

The parties agree to good faith consultation with one another to resolve disagreements that may arise under or relating to this MOA before referring the matter to any other person or entity for settlement.

XI. AUTHORITY, EFFECTIVE DATE, MODIFICATION, AND TERMINATION

A. This MOA is made under the authority of section 319F-2 of the Public Health Service Act, as amended (42 USC § 247d-6b).

B. This MOA shall become effective upon the signature of both parties and shall remain in effect until otherwise agreed to by the parties. The terms of this MOA may be modified upon agreement of both parties. Either party may terminate this MOA at any time upon 180 days advance written notice unless there is a critical failure to perform. In the event of termination, all CHEMPACK Assets and Containers shall be returned to the CDC within 180 days of termination. If the CDC terminates this MOA for a reason other than RECIPIENT'S critical failure to perform, the CDC will, at its own cost, arrange for the return of the CHEMPACK Assets and Containers. The terms and conditions of this MOA will remain in effect until all CHEMPACK Assets and CHEMPACK Containers are returned.

XII. CAPACITY TO ENTER AGREEMENT

The persons executing this MOA on behalf of their respective entities hereby represent and warrant that they have the right, power, legal capacity, and appropriate authority to enter into this MOA on behalf of the entity for which they sign.

_____ _____

Thomas R. Frieden, M.D., M.P.H.
Director, Centers for Disease Control
and Prevention

_____ _____

Date signed Date signed

CHEMPACK Container Contents

EMS CHEMPACK Container for 454 Casualties			
	Unit Pack	**Cases**	**QTY**
Mark 1 auto-injector	240	5	1200
Atropine Sulfate 0.4mg/ml 20ml	100	1	100
Pralidoxime 1gm inj 20ml	276	1	276
Atropen 0.5 mg	144	1	144
Atropen 1.0 mg	144	1	144
Diazepam 5mg/ml auto-injector	150	2	300
Diazepam 5mg/ml vial, 10ml	50	1	50
Sterile water for injection (SWFI) 20cc Vials	100	2	200
Sensaphone® 2050	1	1	1
SATCO C DEA Container	1	1	1

Hospital CHEMPACK Container for 1000 Casualties			
	Unit Pack	**Cases**	**QTY**
Mark 1 auto-injector	240	2	480
Atropine Sulfate 0.4mg/ml 20ml	100	9	900
Pralidoxime 1gm inj 20ml	276	10	2760
Atropen 0.5 mg	144	1	144
Atropen 1.0 mg	144	1	144
Diazepam 5mg/ml auto-injector	150	1	150
Diazepam 5mg/ml vial, 10ml	50	13	650
Sterile water for injection (SWFI) 20cc Vials	100	28	2800
Sensaphone® 2050	1	1	1
SATCO C DEA Container	1	1	1

RECIPIENT Storage and Maintenance Requirements

Consistent with relevant Drug Enforcement Agency and Food and Drug Administration requirements, RECIPIENT agrees to:

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 annual on-site inspections.
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; hand washing 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.

Appendix B
CHEMPACK Formulary

CHEMPACK Formulary
Summary of Data and Assumptions

ATROPEN DATA NOT INCLUDED

Summary and Overall Recommendations:
The following is a summary of the data and assumptions that were used to calculate the CHEMPACK composition. The numbers reflected by using the Department of Defense (DoD) NBC CREST model (Table 4) and using data from other sources (Table 3) are considerably higher than the original estimate for 10,000 casualties. For casualty presentations of mild, moderate, and severe the percentages were weighted to moderate and severe presentations although the modeling suggests that the presentations would be to a greater degree mild to moderate in severity.

Assumptions used in analysis and calculations:

1) Defense Threat Reduction Agency (DTRA) models were used to demonstrate casualty estimates and to extrapolate the percentages of patient presenting mildly, moderately, and severely intoxicated. Two presentations were calculated: 40% mild, 40% moderate, and 20% severe and 30% mild, 40% moderate, and 30% severe.

2) The NBC CREST model utilizes the Department of Defense (DoD) Joint Readiness Clinical Advisory Board (JRCAB) patient treatment protocols to determine their resource requirements. (Table 1).

3) The assumptions used to calculate resource requirements for a civilian response are listed after Table 2. It assumes worst case scenarios and presentations of patients that do not see EMS prior to arrival at a treatment facility.

4) In most cases, each resource requirement was calculated as if it would be needed and utilized and resources were not excluded because it might not be needed or because another resource was available. For instance, diazepam autoinjectors were calculated based on treatment protocols. Diazepam multi-dose vials were calculated based on the fact that no autoinjectors were available. **In other words, there would be overlapping resources for patients if all resources were present for any one patient.**

5) Formulary requirements represent treatment capacity for 100 or 10,000 adults. The pediatric population will be treated with multi-dose vials of atropine, diazepam, and Pralidoxime. Because pediatric treatment is weight based, it would very difficult to estimate the number of children that this formulary could treat.

6) The resource requirements presented in Table 4 represent what is required to **maximally treat 10,000 patients (i.e. maximal medical treatment capability**) because of the overlap in resources, the number of patients that could be treated could exceed 10,000 if not every patient required the maximum use of resources. So that the minimum number of casualties that could be treated is approximately 10,000

where 30% are minimally intoxicated, 40% are moderately intoxicated, and 30% are severely intoxicated. Use of resources and patient severity will affect the total number of casualties that may be treated.

Overall Recommendations:

A: Based on the calculations from Table 2, 6, and 7, **the recommendation is to use the presentation ratio of 30/40/30% mild/moderate/severe.** This heavily weights the presentation to the moderate to severe range and is well within the limits of the casualty modeling done by DTRA.

B: Based on the analysis, the following table represents the requirements of a CHEMPACK formulary for 100 or 10,000 patients:

Table 4 represents formulary requirements if the percentage of mild, moderate, and severe casualties was assumed to be 30% mild, 40% moderate, and 30% severe and Table 2 figures.

Table 4

Resource	**Mild**	**Moderate**	**Severe**	**Total for 100 patients**	**Total10,000 patients**
Mark 1 Kits	45	120	90	255	25,500
Atropine multi-dose	16	12	12	40	2800
Diazepam autoinjector	0	4	45	49	4900
Pralidoxime multi-dose vials	0	148	111	259	25,900
Diazepam multi-dose vial	0	4	60	64	6400

C: Based on the analysis, the following **distribution of CHEMPACK formulary** between first responders/EMS and hospitals/treatment facilities is recommended. State and local preference may dictate other options.

1. **15% of Mark 1 Kits are distributed to treatment facilities.**
2. **15% of multi-dose vials of atropine, diazepam, and Pralidoxime are distributed to first responders/EMS.**

D: Based on the analysis, the following table represents the **treatment capability** of a CHEMPACK per person.

Table 6
mg/person for varying casualty presentations scenarios

Resource	mg/person in formulary for 40/40/20%	**mg/person in formulary for 30/40/30%**	mg/person In formulary for 20/40/40%	Previous NPS Formulary Calculation
Atropine	8.0mg	**8.30**	8.40	8mg
Pralidoxime	3660 mg	**4120 mg**	4580mg	2900mg
Diazepam	7.8mg	**11.3mg**	14.8	30mg

A: Modeling of Chemical Agent Release:
Modeling of chemical agent release was produced by DTRA. DTRA presented a white paper which summarized the scenario of an aerosol release of sarin (GB) in two different situations; a daytime release in a normal population and mass gathering event.

Daytime Release of GB in Seattle, WA (Ct=mg-min/m3)

Ct	# casualties	% casualties	Injury Severity Category	JRCAB Protocol#
> 45	369	.12	severe	#384
45-35	852	.29	severe	#384
34-25	2007	.69	moderate	#383
24-.5	128,967	44.7%	moderate	#383
.5-.3	156,120	54.1%	min. intox	#382

Total 288,315

Mass Gathering Seahawk Stadium Capacity 72,000

Ct	#casualties	%casualties	Injury Severity Category	JRCAB Protocol#
>45	1224	.33	severe	#384
45-35	20,089	5.5	severe	#384
34-25	50,315	13.9	moderate	#383
24-.5	132,567	36.7	moderate	#383
.5-.3	156,120	43.3	min.intoxicated	#382

Total 360,315

Daytime Release of GB in NYC

Ct	#casualties	%casualties	Injury Severity	JRCAB Protocol#
>45	854	.03%	severe	#384
45-35	1083	.04%	severe	#384
34-25	1475	.06%	moderate	#383
24-.05	189,533	.84%	moderate	#383
.49-.3	2,131,377	91.6%	mild	#382

Total 2,324,322

Mass Gathering Central Park (Paul Simon concert)

Ct	#casualties	%casualties	Injury Severity
>45	243,631	8.6	severe
45-35	142,033	5.0	severe
34-25	100,140	3.5	moderate
24-.5	190,757	6.7	moderate
.49-.3	2,131,377	75	mild

Total 2,807,938

Daytime release of GB in Sturgis, SD

Ct	#casualties	%casualties	Injury Severity
>45	238	4.2	severe
45-35	341	6.1	severe
34-25	516	9.2	moderate
24-.5	2,210	39.8	moderate
.49-.3	2,248	40.4	mild

Total 5,553

Mass Gathering Sturgis, SD (Motorcycle Rally)

Ct	#casualties	%casualties	Injury Severity
>45	97,738	19.3	severe
45-35	218,391	43.1	severe
34-25	88,210	17.4	moderate
24-.5	47,510	9.3	moderate
.49-.3	53,704	10.6	mild

Total 505,553

B. Correlation of Ct to symptoms and thus injury severity and JRCAB Patient Codes:

DoD manual AmedP-8 (Chemical) describes the symptomatology associated with chemical exposure at different dose levels. Veridian analyzed this data and determined a correlation between signs and symptoms listed in the Injury Category Tables of AmedP-8 and those in the treatment briefs from JRCAB. This relationship between Ct, Injury Severity and JRCAB Patient Codes are listed in the chart below. It is from this relationship that an idea of resource requirements can be estimated based on JRCAB protocols

Table 1 PC mapping of unprotected exposure to sarin (GB) vapor**.**

AMedP-8 Category Number	Exposure Range Ct (mg-min/m^3)	AMedP-8 Typical Description Injury Severity Category	Component of JRCAB Treatment Briefs	PC Code
1	0 - .25	No obvious injury.	-	-
2	.25 - 3	Nose drips fluid; airway secretions; variable ocular effects from miosis; headache; 10% have ocular or nasal response at 0.3 mg-min/m^3; 50% at 0.5 mg-min/m^3; and 90% at 0.7 mg-min/m^3.	Ambulatory; miosis, lacrimation, salivation, rhinorrhea, none to minimal chest tightness. May have dim vision, eye pain, headache, and nausea	382

AMedP-8 Category Number	Exposure Range Ct (mg-min/m^3)	AMedP-8 Typical Description Injury Severity Category	Component of JRCAB Treatment Briefs	PC Code
3	3 - 6	Eye pain with frontal headache; blurred and dim vision; small pupils; some tightness in chest with increased airway secretions and occasional cough; most signs stop within hours but eye signs may last up to one week.*	"	382
4	6 - 15	Severe headache; eye pain with sensitivity to light and blurred vision, maximal effects in all eyes exposed directly to GB vapor; closing airways with wheezing sounds; nausea/vomiting; weakness; most signs continue for 2 to 3 days but eye effects remain for several days.*	80% ambulatory, 20% assisted, conscious, with miosis, lacrimation, salivation, rhinorrhea, bronchorrhea, chest tightness, weakness, possibly audible wheezes, nausea, vomiting (but no diarrhea).	383
5	15 - 30	Tight chest from closing airways and excessive secretions; coughing; vomiting; abdominal cramps; salivation; severe headache with anxiety and confusion; many have tremors or collapse, some convulse; 10% have severe effects at 23 mg-min/m^3 ; some signs may continue for days or weeks.*	"	383
6	30 - 50	Difficult breathing; weakness; urination; diarrhea; convulsions may be followed by collapse or respiratory failure; 50% have severe effects at 35 mg-min/m^3; 10% die at 45 mg-min/m^3.*	100% assisted. Patient is either unconscious, convulsing, or else has severe effects in two or more of the bodily systems	384

AMedP-8 Category Number	Exposure Range Ct (mg-min/m^3)	AMedP-8 Typical Description Injury Severity Category	Component of JRCAB Treatment Briefs	PC Code
7	50 - 75	Collapse, paralysis or respiratory failure; 90% have severe effects at 55 mg-min/m^3; 50% die at 70 mg-min/ m^3.*	“	384
8	>75	Respiratory failure or unconsciousness; 90% die at 110 mg-min/ m^3.*	“	384

Points to Consider:

1) Data from the first 2 states and 1 city chosen for the CHEMPACK pilot project indicate that the NPS program cannot respond to 100% pf the casualties that present in a daytime release or mass gathering event. **As a result, the limiting factor for procurement of pharmaceuticals should most likely revert back to a question of logistics and finances**.

2) In reviewing the data from DTRA modeling study; it appears that the vast majority of casualties are minimally or moderately intoxicated. The one exception is the Sturgis bike rally where 60% of individuals were severely intoxicated. This suggests that between 40-50% of patients may be able to self-refer to a treatment facility and not need to be treated immediately by EMS. In the Tokyo sarin attack, almost 85% of patients self-referred to the hospital and bypassed the EMS system. However, keep in mind that the sarin was of a very dilute form. Therefore had the concentration been greater, many more patients may have required EMS assistance**. The data suggests that the CHEMPACK be more heavily weighted to multi-dose vials for hospitals than originally thought**.

Assumption for calculation purposes of CHEMPACK composition:

DTRA models were used to demonstrate casualty estimates and to extrapolate the percentages of patient presenting mildly, moderately, and severely intoxicated. Two presentations were calculated: used were 40% mild, 40% moderate, and 20% severe and 30% mild, 40% moderate, and 30% severe This represents a weighting toward more severe intoxication than the first set of data would suggest.

C. Modeling of Resource Requirements:

Modeling of resource requirements has been based in part on the work done by IDA and NBC CREST modelers for Department of the Army, Office of the Surgeon General. The basis for the resource requirements are the JRCAB treatment protocols which have been attached as a reference to this paper. Below are the resource requirements per 100 patients for mild, moderate, and severely intoxicated patient based on modeling by NBC CREST and IDA.

Table 1
Resources Required Per 100 Patients
By NBC CREST

Resource	Mild (PC 382)	Moderate (PC383)	Severe (PC384)
Mark 1 Kits	152	400	705
Atropine .4mg/cc 20cc vial	1	6	39
Diazepam Autoinjector			480
Pralidoxime Autoinjector 600mg			22
Diazepam Multi-dose Vial 5mg/cc 10cc vial			8

Of note the large numbers of Mark 1 Kits required are based on military treatment and the assumption that as many as 7 kits could be used to treat a soldier under medical supervision. Thus Mark 1 Kits would be used in the hospital setting over multi-dose vials in many instances.

Below are the Resource requirements that have been estimated per 100 patients based on JRCAB protocols, NBC CREST, clinical experience, and Tokyo Sarin Attack. The assumptions needed for the calculations are listed below the chart.

Table 2
Resources Required per 100 Patients
Multiple Data References

Resource	Mild (PC 382)	Moderate (PC383)	Severe (PC384)
Mark 1 Kits	150	300	300
Atropine .4mg/cc 20cc vial	51	30	40
Diazepam Autoinjector	0	10	150
Pralidoxime 1gm powdered vial	0	370	370
Diazepam Multi-dose Vial 5mg/cc 2cc vial	0	10	200

Assumptions:

1) **Mark 1 Kits**- For a mild intoxicated patient, at minimum one Mark 1 Kit is needed. According to JRCAB protocols, 50% may require additional Mark 1 Kit; therefore for 100 patients 150 kits are required. For a moderately intoxicated patient, based on JRCAB protocols, these patients may require up to 3 Mark 1 Kits, therefore for 100 patients 300 Mark 1 Kits are needed. For severely intoxicated patients, 3 Mark 1 kits for each patient, therefore 300 kits. Unlike in the military setting where additional Mark 1 Kits may be used in the hospital setting, it is more likely that multi-dose vials will be utilized in a civilian

setting. As a result, no more than 3 Mark 1 kits per patient were considered necessary. Additional treatment would be accomplished with multi-dose vials. *See additional consideration on page 10*.

2) **Atropine multi-dose vial**: The first assumption is that mildly intoxicated patients may be able to reach the hospital without treatment by EMS. Therefore, the 150 Mark 1 kits is equivalent to 300mg of atropine which is 37.5 vials (rounded up to 38 vials). Per JRCAB protocols, it is estimated that 50% of mildly intoxicated patients will require additional atropine. If 50 patients require an additional 2 mg of atropine than 100mg of atropine would be required. This is equal to 12.5 vials (rounded up to 13) of multi-dose atropine. **Therefore the total number of vials of atropine for mildly intoxicated patients is 51 (13+38) vials**. For the moderately and severely intoxicated patient, the assumption is that they will require assistance by EMS and therefore receive prior atropine treatment in the form of Mark 1 kits prior to arrival in the hospital The vast majority of victims in the sarin Tokyo attack required only 2 mg of atropine. Only 19% of the moderate to severely intoxicated patients required more than 2 mg. For moderately intoxicated patients, an assumption is that 100% of patient would require an additional 2 mg of atropine or 200mg of atropine which is equal to 25 vials. And 20% of patients would require 4 mg i.e. 20 patients need an additional 2 mg of atropine. This requirement is 40mg or 5 vials. **Total vials = 30 for moderately intoxicated**. For severely intoxicated, 100% of patients would require 2 mg of atropine following the use of Mark 1 kits or 200mg each to 25 vials of atropine. And 20% of patients would require 8 mg, i.e. 20 patients need an additional 6 mg of atropine. This requires 120 mg of atropine or 15 vials. **Total vials for severely intoxicated patient is 40.**

3) **Diazepam autoinjector**: No autoinjectors are anticipated to be required for patients that present with mild intoxication. It is estimated that 10% of patients might have seizures at a moderate intoxication; therefore 10 auto injectors would be required. For severely intoxicated individuals, it is anticipated that 1 diazepam autoinjector is needed for each patient and that 50% require more than 1 autoinjector; therefore 150 diazepam autoinjectors are needed.

4) **Pralidoxime**: Additional Pralidoxime is not anticipated to be needed for mildly intoxicated patients. For moderately intoxicated patients, JRCAB protocols do not indicate the need for additional Pralidoxime following the use of 3 Mark 1 kits. However, it is possible that patients will arrive at the hospital prior to receiving 3 Mark 1 kits in a civilian setting. In the Tokyo sarin attacks, 95% of the moderate to severely intoxicated patients received doses of 0-8 grams of Pralidoxime. According to the Medical Management of Chemical Casualty Handbook, 2-3 additional doses of Pralidoxime may be required at a dose of 1gm/patient. Wetter et al estimated that at least 2 grams of Pralidoxime would be needed in 95% of moderately to severe casualties. Given this data and assuming that some patients that present to a treatment facility have not received 3 Mark 1 kits and a requirement of 2gm of Pralidoxime for 95% of

moderately intoxicated patient. The vial requirements would be 190 vials (2gm for 95 patients) and would require 1800mg Pralidoxime for 100 patients (equivalent to 3 Mark 1 kits) or 180 vials. Total for a moderate intoxicated patient is 370 vials. The requirements for severely intoxicated patients may be similar or slightly higher.

5) **Diazepam Multi-dose**: Mildly intoxicated patients would not be expected to require diazepam. Ten percent of moderately intoxicated patients might be expected to require diazepam per JRCAB protocols. If an autoinjector were not available, this treatment would need to be provided by a multi-dose vial. The dose of the autoinjector is 10mg IM. Therefore, 10 patients will require 10mg of diazepam or 100mg which is equal to 10 vials. For severely intoxicated patient, JRCAB protocols require 100% patients receive 1 diazepam autoinjector and 50% of patients require an additional autoinjector for a total of 150 autoinjectors. Additionally some patients will require additional diazepam. Assuming that 100% of severely intoxicated patients did not have access to autoinjector from EMS and additional diazepam was required by hospital personnel; 100 patients will require 10mg/each or 1000mg total of diazepam, and 100% of patients will require 10mg of diazepam in the treatment facility in addition to any treatment they may have received prior to arrival, this requires 10mg of diazepam per 100 patients or 1000mg diazepam. The total mg requirement is 2000mg or 200 vials.

Calculation of the Resource Requirements for 100 and 10,000 patients based on a casualty presentation of 40% mild, 40% moderate, and 20% severe intoxicated patients. Calculations are based on Table 2 and the above percentages.

Table 3

Resource	Mild	Moderate	Severe	Total for 100 Patients	Total for 10,000 patients
Mark 1 Kits	60	120	60	240	24,000
Atropine multi-dose	21	12	8	41	4100
Diazepam autoinjector	0	4	8	12	1200
Pralidoxime multi-dose vials	0	148	74	222	22,200
Diazepam multi-dose vial	0	4	40	44	4400

Table 4 represents formulary requirements if the percentage of mild, moderate, and severe casualties was assumed to be 30% mild, 40% moderate, and 30% severe and Table 2 figures.

Table 4

Resource	Mild	Moderate	Severe	Total for 100 patients	Total for 10,000 patients
Mark 1 Kits	45	120	90	255	25,500
Atropine multi-dose	16	12	12	40	4000
Diazepam autoinjector	0	4	45	49	4900
Pralidoxime multi-dose vials	0	148	111	259	25,900
Diazepam multi-dose vial	0	4	60	64	6400

Calculation of the Resource Requirements for 100 and 10,000 patients based on a casualty presentation of 40% mild, 40% moderate, and 20% severe intoxicated patients. Calculations are based on Table 1 and the above percentages. (Based on NBC CREST)

Table 5

Resource	Mild	Moderate	Severe	Total for 100 Patients	Total for 10,000 patients
Mark 1 Kits	61	160	141	362	36,200
Atropine multi-dose	1	3	8	12	1200
Diazepam autoinjector	0	0	96	96	9600
Pralidoxime multi-dose vials	0	0	5	5	500
Diazepam multi-dose vial	0	0	2	2	200

The Table 3 and 4 compared to Table 5 to some degree represent a difference in patient management from civilian (Table 3,4) to military doctrine and the military reliance on primarily autoinjectors (Table 5).

Table 6
mg/person for varying casualty presentations

Resource	mg/person in formulary for 40/40/20%	mg/person in formulary for 30/40/30%	mg/person In formulary for 20/40/40%	Previous NPS Formulary Calculation
Atropine	8.0mg	8.30mg	8.4mg	8mg
Pralidoxime	3660 mg	4120 mg	4580mg	2900mg
Diazepam	7.8mg	11.3mg	14.8	30mg

Table 6 represents the treatment capability that the CHEMPACK provides on average per person depending on the scenario percentages chosen. In reviewing this information, the science team would recommend a treatment capability based on 30/40/30% casualty distribution.

Other Considerations:

In general the calculations in Table 3 and Table 4, assume that there is access to a Mark 1 kit for treatment of chemical casualties. It is also presumed that this treatment has occurred via field medic, trained soldier, or EMS prior to arrival to a first aid station or treatment facility. Therefore, below are certain other considerations when reviewing the requirements.

Mark 1 kit- The Mark 1 kits were calculated on the basis that no kits would be used in the hospital in a civilian setting. However, it is unrealistic to expect 100% of patients requiring medical treatment to be evaluated by EMS or first responders. One consideration is to distribute a certain percentage of those kits for in-hospital usage or add an additional percentage (10-15%) for in hospital use*. See distribution of CHEMPACK formulary*

Pralidoxime- The severely intoxicated patient may require more Pralidoxime than is calculated for in Table 3 for several reasons. First, their clinical requirement may be more than 2gm per patient. In the Sarin Tokyo attacks, some patients received as much as 8gm per patient. Secondly, the JRCAB protocols assume that the patients have received Mark 1 kits prior to the presentation to the hospital. Additional multi-dose vials of Pralidoxime could be added to the severe presentation category or a certain percentage of the Mark 1 kits calculated could be dispersed into the hospital setting.

Distribution of CHEMPACK Formulary:

There are essentially two end users for this CHEMPACK formulary; the first responders/EMS services and the treatment facility/hospital. In deciding where the formulary should be distributed, certain considerations should be taken into account;

1. What do the individual states/cities expect and perceive their response to a mass casualty situation to be? Is this realistic?

2. What percentage of patients will actually be seen and treated by EMS? The sarin Tokyo attack demonstrated that 85% of patients self-referred to the hospital and were never evaluated by EMS. If the concentration of sarin had been higher, one could have expected more severe casualties and higher percentage requiring EMA services. However, placing 100% of the Mark 1 kits at the EMS level, assumes that the only patients seen by EMS could benefit from this treatment. In addition, the calculating the formulary requirement to a certain extent was based on the assumption that Mark 1 kits were available for overall patient treatment including those not seen by EMS. Given the above considerations, I would recommend that 15% of the Mark 1 kits or that percentage needed to treat mildly intoxicated patients (45 kits divided by 255 Mark 1 kits = 17.6%, i.e. 30 patients of 100 casualties are assumed to be mildly intoxicated and require at least one antidote kit) be distributed into the treatment facility. This allows treatment facilities the option of treating people with an IM medication quickly and gives an option to the provider when an IV line cannot be established or when time does not permit a line to be established. Further this also reduces the redundancy in requirements for the CHEMPACK to have additional Pralidoxime and atropine for those patients that would have received a Mark 1 kit per the JRCAB protocol. Of note, hospitals in Israel have Mark 1 kits in their formulary.

3. What training does EMS or hospital providers have in using Mark 1 kits? Medical providers must be comfortable using this autoinjector or it can become a wasted resource. What training is the state planning on providing for Mark 1 kits and overall treatment of chemical casualties by EMS providers? Does the EMS system have treatment protocols in place to use Mark 1 kits?

4. Are treatment facilities or hospitals willing to store and maintain portions of the CHEMPACK? Will hospital providers receive training in Mark 1 kits?

5. How should the distribution of the multi-dose vials occur? Hospitals or treatment facilities would benefit greatly from additional multi-dose atropine and Pralidoxime as studies have shown that most hospitals stockpile no more than 2 grams of Pralidoxime at any one time. However, giving 100% of the multi-dose vials to the treatment facilities would severely limit the EMS/first responders' ability to treat pediatric patients as Mark 1 kits are should not be used in children under 10 years old according to the PDR. According to the 2000 US. Census Data, the population of children under 10 years of age is 16.1%. Given this data, approximately 15% of the multi-dose vials could be made available to first responders/EMS.

Appendix C
Environmental Standards for Cache Storage Requirements

Temperature: Mean Kinetic Temperature (MKT) 68-77 degrees Fahrenheit

Humidity: relative humidity below 60%-the level required for mold growth; ideally relative humidity should be maintained between 30-50%, EPA standard.

Lighting: Adequate lighting for the occupant use of the building or at least as required for reading instructions, placards and carton labeling (OSHA standard).

Ventilation: Adequate ventilation for the occupant use of the building (ASHRAE standard).

Sanitation: Pharmaceutical storage areas must be clean, free from infestation by insects, rodents, birds, or vermin of any kind.

Security:

Limited Entry: Entry must be limited to authorized personnel; controlled access or keyed entry is acceptable methods to limit access.

Alarms: Cache locations not continuously monitored, 24 hours a day, 7 days a week, must have a monitored alarm system able to detect unauthorized entry and provide notification to designated personnel from each facility. Potential systems include video cameras, motion detectors, or contact alarms, providing the system is able to notify appropriate facility personnel when unauthorized entry is made.

Facility Contacts: The DSNS program must have current contact information for facility personnel designated to respond to security alarms and/or other environmental conditions.

Appendix D

CHEMPACK TRAINING CONTAINER REQUEST PROTOCOL

Purpose: To establish New York State procedures for requesting, deploying, and utilizing the CHEMPACK training containers of the Division of Strategic National Stockpile (DSNS) Program.

Authorization: The mission of the DSNS Program is to deliver critical medical assets to the site of a national emergency; when directed by the Department of Homeland Security, and in consultation with the Department of Health and Human Services. The CHEMPACK PROJECT is a subset of the DSNS program. The mission is to "forward" place nerve agent antidotes to provide state, county and local governments sustainable resources; and improve their capability to respond quickly to a nerve agent attack.

Administration of the CHEMPACK PROJECT is the responsibility of the New York State Department of Health (NYS DOH).

General: Emergency response operations require frequent, interagency training exercises for cohesive and effective response. State, county and local agencies should incorporate CHEMPACK into nerve agent emergency response drills. However, the DSNS Program does not want state, county or local personnel to move, open, or train with actual CHEMPACK containers. To meet and encourage training needs, the DSNS developed CHEMPACK training containers.

Procedures: CHEMPACK training containers will be made available by the New York State Department of Health. There is one hospital configuration container and one EMS configuration container.

When county agencies are planning exercises involving CHEMPACK assets, they must include their supporting Hub Hospital in the planning process. The request for a CHEMPACK training container shall be made by the established CHEMPACK PROGRAM ***Point of Contact***, or alternate, of the hub hospital involved in the planned exercise

CHEMPACK training containers shall be requested by completion of the NYS DOH CHEMPACK TRAINING UNIT REQUEST form and faxing the completed form to: (518) 402-6228

CHEMPACK training container requests shall be accompanied by an outline of the planned exercise. Of special interest will be a list of goals and objectives.

Once a request is received NYS DOH personnel will:

- Check the availability of the container(s) and,
- Compliance with this protocol.

Requests will be answered by e-mail to the requesting hub hospital POC.

Responsibilities: NYS DOH personnel shall arrange the delivery and retrieval of the training container(s).

Training containers shall **ONLY** be delivered to the hub hospital.

NYS DOH personnel shall load each requested container with like size and weight boxes, labeled appropriately, in accordance with the participating hospital's CHEMPACK inventory schedule. All training material must be returned to the container after the exercise for return to NYS DOH.

Hub hospital personnel shall make arrangements for the safe unloading and loading of the training container(s) at their location.

Training containers should be located as close to the actual CHEMPACK storage area as practical.

CHEMPACK training containers shall only be opened, and supplies distributed, by those authorized by established procedure.

Hub hospital personnel shall be responsible for the return of all contents of the training container(s).

Summary: Emergency response drills are an essential component of preparedness. Drill facilitators should integrate all partners at the planning stage in order to maximize the exercise's effectiveness.

An after-action report/summary report shall be forwarded to the CHEMPACK e-mail address for documentation and review.

Appendix E
CHEMPACK Weights and Volumes

HOSPITAL CHEMPACK TYPE 1						
PRODUCT	**H1 (RED)**		**H2 (GREEN)**		**H3 (BLUE or YELLOW)**	
	Vol	**Wgt**	**Vol**	**Wgt**	**Vol**	**Wgt**
Mark 1 Autoinjectors	2 cf	40 lbs	2 cf	40 lbs	0	0
Atropine Sulfate	1 cf	30 lbs	1 cf	20 lbs	1 cf	20 lbs
Pralidoxime	2 cf	39 lbs	2 cf	39 lbs	4 cf	59 lbs
Atropen .5mg	1 cf	3 lbs	1 cf	3 lbs	1 cf	3 lbs
Atropen 1.0mg	1 cf	3 lbs	1 cf	3 lbs	1 cf	3 lbs
Diazepam Autoinjectors	1 cf	20 lbs	0	0	0	0
Diazepam 5mg/ml vial	1 cf	7 lbs	1 cf	7 lbs	1 cf	6 lbs
Sterile Water for injection	6 cf	138 lbs	6 cf	138 lbs	4 cf	103 lbs
TOTALS	15 cf	279 lbs	14 cf	249 lbs	11 cf	194 lbs

HOSPITAL CHEMPACK TYPE 2								
PRODUCT	**H3 (BLUE or YELLOW)**		**H4 (ORANGE)**		**E1 (GREEN)**		**E2 (RED)**	
	Vol	**Wgt**	**Vol**	**Wgt**	**Vol**	**Wgt**	**Vol**	**Wgt**
Mark 1 Autoinjectors	0	0	0	0	4 cf	79 lbs	0	0
Atropine Sulfate	1 cf	20 lbs	1 cf	20 lbs	1 cf	10 lbs	1 cf	20 lbs
Pralidoxime	4 cf	59 lbs	2 cf	39 lbs	1 cf	20 lbs	1 cf	20 lbs
Atropen .5mg	1 cf	3 lbs	1 cf	2 lbs	1 cf	3 lbs	1 cf	2 lbs
Atropen 1.0mg	1 cf	3 lbs	1 cf	2 lbs	1 cf	3 lbs	1 cf	2 lbs
Diazepam Autoinjectors	0	0	0	0	1 cf	20 lbs	0	0
Diazepam 5mg/ml vial	1 cf	6 lbs	1 cf	5 lbs	1 cf	6 lbs	1 cf	5 lbs
Sterile Water for injection	4 cf	103 lbs	4 cf	103 lbs	3 cf	69 lbs	4 cf	103 lbs
TOTALS	11 cf	194 lbs	10 cf	171 lbs	13 cf	207 lbs	9 cf	152 lbs

CHEMPACK Weights and Volumes

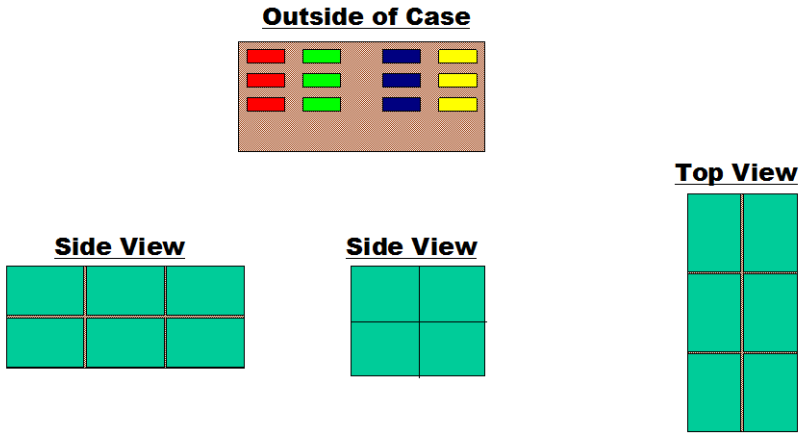
EMS CHEMPACK TYPE 1				
PRODUCT	E3 (ORANGE)		E4 (BLUE)	
	Vol	Wgt	Vol	Wgt
Mark 1 Autoinjectors	10 cf	198 lbs	12 cf	237 lbs
Atropine Sulfate	1 cf	10 lbs	0	0
Pralidoxime	1 cf	20 lbs	0	0
Atropen .5mg	1 cf	12 lbs	1 cf	12 lbs
Atropen 1.0mg	1 cf	12 lbs	1 cf	12 lbs
Diazepam Autoinjectors	2 cf	40 lbs	2 cf	40 lbs
Diazepam 5mg/ml vial	1 cf	2 lbs	1 cf	2 lbs
Sterile Water for injection	1 cf	34 lbs	1 cf	17 lbs
TOTALS	19 cf	327 lbs	19 cf	320 lbs

EMS CHEMPACK TYPE 2				
PRODUCT	E5 (YELLOW)		H5 (WHITE)	
	Vol	Wgt	Vol	Wgt
Mark 1 Autoinjectors	14 cf	277 lbs	8 cf	158 lbs
Atropine Sulfate	0	0	1 cf	10 lbs
Pralidoxime	0	0	1 cf	20 lbs
Atropen .5mg	1 cf	12 lbs	1 cf	12 lbs
Atropen 1.0mg	1 cf	12 lbs	1 cf	12 lbs
Diazepam Autoinjectors	2 cf	40 lbs	2 cf	40 lbs
Diazepam 5mg/ml vial	1 cf	2 lbs	1 cf	2 lbs
Sterile Water for injection	1 cf	17 lbs	1 cf	34 lbs
TOTALS	21 cf	360 lbs	18 cf	288 lbs

CHEMPACK Weights and Volumes

The case of Atropen Autoinjectors contains 12 boxes with 12 autoinjectors each. Upon a decision to open the CHEMPACK container, the Atropen boxes will have to be removed from the packaging case at that point and distributed according to the color scheme on the outside of the case.

ATROPEN Breakdown Procedures



APPENDIX F
RESPONSE PROTOCOLS

1. OVERVIEW

2. CONTACT REPORT FORM

3. STORAGE ISSUES

- **A. LOW TEMPERATURE**
- **B. HIGH TEMPERATURE**
- **C. POWER INTERRUPTION**
- **D. TELEPHONE INTERRUPTION**
- **E. SECURITY BREACH**

A. OVERVIEW

As part of ongoing efforts to ensure the integrity and security of the CHEMPACK program in New York State (NYS), the Department of Health (DOH) has developed a protocol for contacting Hub Hospitals in New York State.

This protocol is designed for those times it becomes necessary for CDC, NYSDOH, or a local County Office of Emergency Management (OEM) to contact the hospital directly. It is to be utilized only when an immediate response is warranted as a result of an alert caused by a change in the CHEMPACK container's status or storage conditions. The goal is to have someone physically respond to the CHEMPACK room within fifteen (15) minutes of contact.

Unless circumstances dictate otherwise, most normal, administrative contacts will go through the NYSDOH representative designated as the State's Point of Contact (POC) or Alternate Point of Contact (APOC). These contacts are for normal business during normal business hours.

B. CONTACTING A HUB HOSPITAL

For security reasons, if a Hub Hospital cannot verify the caller as an agency representative authorized to contact them, they will NOT acknowledge the CHEMPACK Program. They will ask for your name, agency, and a call back number. They will then contact NYSDOH designated POC or APOC, who will in turn contact you.

1. AUTHENTICATION INFORMATION

When contacting hospitals in New York State the following information is required:
(Follow the sample script outlined below.)

Hospital Name
CHEMPACK four-digit container number
Hospital four-digit PFI number
Hospital ten-digit authentication code.

2. SCRIPT

a. This is _____ (your name) from the _____ (agency, i.e.; CDC in Atlanta). I am calling regarding a CHEMPACK issue.

The hospital will ask you for the required information. Provide them with the name of their hospital, the container number, their PFI number, and the authentication code.

If the name of the hospital, container number, PFI or authentication code information does not match, the hospital will NOT acknowledge the CHEMPACK Program, but will ask for your name, agency, and call back number. They will then terminate the call and contact a NYSDOH representative. The NYSDOH representative will contact you. This is a vital security link that helps maintain the integrity of the program.

Once your identity and the information are verified explain the reason for the call.

b. I am calling regarding a CHEMPACK condition that needs your immediate attention. We have a/an _____ (Please use one of the following categories):

A. Environmental Concern (Temperature/humidity getting too high/low)
B. Power interruption/lost
C. Sensaphone telephone contact interrupted/lost
D. Container Opened
E. Other/Miscellaneous (Please describe the problem)

c. The call taker will verify your call back information and put you on hold while they contact the appropriate hospital representative. If they cannot contact someone immediately, they may have someone call you back.

When speaking with the hospital representative, you should;

d. Identify yourself, your organization, your call back number, and the problem.

e. Ensure the hospital representative has your name and call back information, as they will be going to physically check on the CHEMPACK Container and may have to call you back.

f. The hospital representative will call you back with a condition report and explain the action steps taken or discuss the action steps needed.

g. Once the action steps are complete, the hospital will confirm that the correction has been successful to close the issue. (i.e., power restored, temperature changing to appropriate level)

3. INSUFFICIENT RESPONSE

a. If the call taker is unable or unwilling to contact the appropriate hospital representative, or the representative is unable or unwilling to make the required changes, please obtain their name and call back number. Contact the designated NYSDOH POC or APOC to intercede and facilitate the appropriate action steps.

b. If the action steps do not correct the situation, and you are unable to progress toward a positive solution with hospital personnel, please obtain their name and call back number and contact the designated NYSDOH POC or APOC to intercede and facilitate the appropriate action steps.

4. FOLLOW UP

Upon completion of any contact with a hub hospital please generate an email to the NYS Program Mangers for both Hospital BT Preparedness and Public Health Preparedness with a summary of the events and the outcome. <chempackny@health.state.ny.us>

STATE OF NEW YORK DEPARTMENT OF

CHEMPACK CONTACT REPORT

Complete for any CHEMPACK Contacts
For NYSDOH Staff Use Only

TO BE COMPLETED BY PERSON WHO RECEIVES THE CALL		
Date:	Time Call Received:	
Call Received by:		
Caller's Organization: (Check one) ☐ CDC ☐ NYSDOH ☐ County OEM		
Call Back Number: Extension:		
Reason for Contact:		
LOCATION OF CHEMPACK ALARM		
Hospital Name:	Region:	
Street Address:	City:	
Phone:	Time Contacted:	
Responders Name:		
Responders Position:		
Alternate Phone:		
ACTION TAKEN BY RESPONDER		
Physically Checked CHEMPACK ☐ Yes ☐ No	Time:	
Condition Upon Inspection:		
Corrective Action Taken:		
Time Correction Made:	Correction Confirmed With:	Time Confirmed:
CHEMPACK Room Secured: ☐ Yes ☐ No	Time:	

STORAGE ISSUE REQUIRING ACTION STEPS

CALL RESPONDER

► ONLY NYSDOH, CDC, OR YOUR COUNTY OEM ARE AUTHORIZED TO CONTACT YOU REGARDING CHEMPACK ◄

The _____ (Facilities/Security/Nursing Supervisor) will accept the call and:

1. VERIFY REASON FOR CALL

The caller should give you the following information:

1. Their name, organization, and call back number
2. The condition that needs attention
    a. Environmental Concern (Temperature/humidity getting too high/low)

2. ACTION STEPS

1. Obtain keys to the CHEMPACK room
2. Notify Security that you will be entering the CHEMPACK room
3. Follow instructions below

A. ENVIRONMENTAL

1. Physically respond to the CHEMPACK room within 15 minutes of contact
2. Check room temperature via thermostat
3. Check Container temperature by reading the Min/Max in the container
4. If temperature has risen or dropped, adjust thermostat accordingly
5. If thermostat not working replace immediately
6. Monitor temperature to ensure correction is occurring
7. Call original caller to discuss actions and verify correction is occurring
8. Obtain partially completed Contact Report from call taker
9. Complete remainder of Contact Report
10. E-mail or fax Contact Report to NYSDOH @ chempackny@health.state.ny.us or 518-402-8659
11. Monitor CHEMPACK room periodically for next 48 hours to ensure correction is maintained

POWER CONCERN

CALL RESPONDER

► ONLY NYSDOH, CDC, OR YOUR COUNTY OEM ARE AUTHORIZED TO CONTACT YOU REGARDING CHEMPACK ◄

The _____ (Facilities/Security/Nursing Supervisor) will accept the call and:

1. VERIFY REASON FOR CALL

The caller should give you the following information:

1. Their name, organization, and call back number
2. The condition that needs attention
    b. Power Concern (Power interrupted or lost)

2. ACTION STEPS

1. Obtain keys to the CHEMPACK room
2. Notify Security that you will be entering the CHEMPACK room
3. Follow instructions below

B. POWER

1. Physically respond to the CHEMPACK room within 15 minutes of contact.
2. Check the power cords, plugs and outlets; reconnect if they came unplugged, reset if tripped
3. Ensure that back up generator has started (If outage lasts more than a minute)
4. If unable to immediately restore power, contact appropriate facilities person to restore the power by whatever means necessary
5. Call original caller to discuss actions taken and verify correction is occurring
6. Complete remainder of Contact Report
7. E-mail or fax Contact Report to NYSDOH at chempackny@health.state.ny.us or 518-402-8659
8. Monitor periodically for next 48 hours to ensure correction is maintained

SENSAPHONE CONCERN

CALL RESPONDER

► ONLY NYSDOH, CDC, OR YOUR COUNTY OEM ARE AUTHORIZED TO CONTACT YOU REGARDING CHEMPACK ◄

The _____Facilities/Security/Nursing Supervisor will accept the call and:

1. VERIFY REASON FOR CALL

The caller should give you the following information:

1. Their name, organization, and call back number
2. The condition that needs attention
    c. Sensaphone Concern (Contact interrupted or lost)

2. ACTION STEPS

1. Obtain keys to the CHEMPACK room
2. Notify Security that you will be entering the CHEMPACK room
3. Follow instructions below

C. SENSAPHONE

1. Physically respond to the CHEMPACK room within 15 minutes of contact
2. Check the Sensaphone to see if lights are on
3. Check telephone line connections from pack to wall jack
4. If unplugged, plug back in
5. If unable to restore Sensaphone connection, contact appropriate facilities/technology person to restore the phone service or have them contact you telephone service provider for an emergency repair
6. Call original caller to discuss actions taken and verify correction
7. Complete Contact Report
8. E-mail or fax Contact Report to NYSDOH @ chempackny@health.state.ny.us or 518-402-8659
9. Monitor periodically for next 48 hours to ensure correction is maintained

SECURITY CONCERN

CALL RESPONDER

► ONLY NYSDOH, CDC, OR YOUR COUNTY OEM ARE AUTHORIZED TO CONTACT YOU REGARDING CHEMPACK ◄

Facilities/Security/Nursing Supervisor will accept the call and:

1. VERIFY REASON FOR CALL

The caller should give you the following information:

1. Their name, organization, and call back number
2. The condition that needs attention
    d. Security Concern (Intrusion Alert or Container opened)

2. ACTION STEPS

1. Obtain keys to the CHEMPACK room
2. Request Security accompany you to the CHEMPACK room
3. Follow instructions below

D. CONTAINER OPENED

1. Physically respond to the CHEMPACK room IMMEDIATELY
2. Check to see if the CDC plastic seal and the padlock are still in place
3. If seal and lock are in place, check the colors of the Sensaphone lights
4. Call original caller back and discuss events found
5. If CHEMPACK is opened without a hospital activation, TOUCH NOTHING, REMOVE ALL PERSONNEL FROM THE ROOM TO PRESERVE THE ROOM AS A CRIME SCENE.
6. NOTIFY THE LOCAL LAW ENFORCEMENT AGENCY
7. IMMEDIATELY notify the NYSDOH and await further instructions.
8. Alert all appropriate Hospital and Security Personnel about the breach in security and watch for potential perpetrators attempting to leave the building with CHEMPACK assets
9. Post Security Personnel at the CHEMPACK Room door
10. Do not let anyone else enter the room unless instructed to do so by NYSDOH, CDC or Law Enforcement
11. Start a log with date, names and positions of all who already have or who enter the CHEMPACK Room noting time in and time out and purpose of their entry
12. Complete Contact Report
13. E-mail or fax Contact Report to NYSDOH @ chempackny@health.state.ny.us or 518-402-8659

OTHER/MISCELLANEOUS CONCERN

CALL RESPONDER

► ONLY NYSDOH, CDC, OR YOUR COUNTY OEM ARE AUTHORIZED TO CONTACT YOU REGARDING CHEMPACK ◄

The _____ (Facilities/Security/Nursing Supervisor) will accept the call and:

1. VERIFY REASON FOR CALL

The caller should give you the following information:

1. Their name, organization, and call back number
2. The condition that needs attention
    e. Other/miscellaneous (They should describe the problem)

2. ACTION STEPS

1. Obtain keys to the CHEMPACK room
2. Notify Security that you will be entering the CHEMPACK room
3. Follow instructions below

E. OTHER/MISCELLANEOUS

Any time something happens like a power outage, telephone service disruption, change in weather, severe weather, or plant modifications, someone should check on the status of the CHEMPACK. This may or may not be preceded by a call from NYSDOH or CDC.

1. Physically respond to the CHEMPACK room within 15 minutes of contact
2. Check appropriate conditions for the described problem or other concern
3. Make adjustments as needed
4. Call original caller back to discuss actions taken
5. Complete Contact Report if call received
6. E-mail or fax Contact Report to NYSDOH @ chempackny@health.state.ny.us or 518-402-8659
7. Contact NYSDOH prior to changes occurring for advanced arrangements

APPENDIX G
New York State CHEMPACK SPECIAL EVENT CONTAINERS

An act of chemical terrorism, or large scale industrial disaster, targeting the NYS population requires rapid access to large quantities of antidotes and medical supplies. Such quantities may not be readily available unless special stockpiles are available. No one can anticipate exactly where a terrorist will strike. Therefore, in addition to the Centers for Disease Control and Prevention (CDC) CHEMPACK containers located throughout the state, a NYS Special Event cache stockpile has been created.

2. NYS has established a cache of two EMS-type and two Hospital-type CHEMPACK containers for high profile or other special events where large crowds of people attending special events may present a higher danger of chemical attack and the normal placement of CHEMPACK supplies may not be adequate. These high profile or special events are not regular events such as football games, concerts, etc., but events of national or international significance. The CHEMPACK containers may be moved from the storage location to special events if necessary. However, NYS must maintain the established environmental conditions of the CHEMPACK containers at all times. NYS must use special cargo transport vehicles with environmental systems and will pay for the movement of the CHEMPACK containers to support the special events. However, there are ancillary costs that will be the responsibility of the requesting agency, such as phone lines and door alarms and possibly others. All such moves must be coordinated with the CDC CHEMPACK staff prior to execution. In cases of multiple qualifying special events, the cache containers will be deployed on the basis of statewide priorities based on threat assessment.

3. Any County hosting a special event may request the containers for the duration of the event. All requests received from the counties will be fully evaluated based upon the information presented by the County to justify their request. A sample request form is attached. The County is responsible for selecting a site that meets the environmental and security requirements set forth by CDC. The site will be jointly inspected by NYS Department of Health and the county prior to the deployment. Additionally, the County must identify a DEA licensed individual to temporarily sign for custody of the CHEMPACK container(s). Once deployed, the county will be responsible for any costs associated with the temporary storage of the CHEMPACK container.

4. All County requests for special event use of the CHEMPACK cache containers should be coordinated with appropriate county agencies and then sent from County Emergency Management/Services Offices to the NYS Emergency Management Regional Office. NYS Emergency Management Officials will coordinate the requests with NYS Department of Health Officials to reach a consensus on the deployment.

APPENDIX G
NYS CHEMPACK CACHE SPECIAL EVENT REQUEST

County making the request: _____

Special Event Title: _____

Dates of the Special Event: _____

Number of People Expected to attend the event: _____

Proposed temporary CHEMPACK storage location including response protocols for temperature/security alerts: _____

_____

Proposed DEA-registered custodian: _____

Nearest current CHEMPACK Hub Hospitals: _____

Why current hub CHEMPACKs won't meet the needs as envisioned by the County:

_____

_____

Explain the plan in place for utilizing the current hub/spoke CHEMPACK assets?

_____

Explain the plan for use and/or distribution of the assets in the event of an attack?

_____

_____

Justification for request of assets: _____

_____

Impact if CHEMPACK containers are not pre-positioned: _____

_____

Appendix H
CHEMPACK Opening Protocol

CHEMPACK is part of the DSNS program. Therefore, if an incident calls for opening a CHEMPACK, then the DSNS request channels should be initiated. The locality first declares an emergency and notifies the County who then declares an emergency and notifies the State. The State declares an emergency and requests assets from CDC.

CHEMPACK assets are utilized during an emergency to save life when all other hospital resources have been exhausted.

There are three (3) *emergency scenarios* that generate a request to open a CHEMPACK

1. A hub hospital has a surge of patients in the ED that require a nerve agent antidote and the hospital has exhausted it supply of nerve agent antidotes. The ED physician consults with the pharmacist (or his/her designee) and makes the determination to open the CHEMPACK and access the pharmaceuticals to treat patients. Then the hospital activates its emergency plan which starts the HEICS and notifies the County Office of Emergency Management/Local Health Department (OEM/LHD). If there is a surge of patients requiring nerve agent antidotes, then it should be assumed that other hospitals would be affected. The county OEM/LHD should activate its response to include opening its Emergency Operations Center and notifying the State.

2. The county OEM/LHD contacts the hub hospital and asks it to open the CHEMPACK and get a partition(s) to the designated pick up area (loading dock door, ED door). There whomever has been authorized by the county will pick up the partition and deliver it. This request should be made utilizing the color-coded labels affixed during the placement of the CHEMPACK containers. (Ex. Place the green and yellow boxes at the door.) The hospital should also activate its own emergency plan and anticipate a surge of patients needing nerve agent antidotes or follow up treatment.

3. NYS contacts the hub hospital and makes arrangements to move the entire CHEMPACK container out of the hospital. The hospital should then review the path to the loading dock door and clear it of any obstructions that might interfere with moving the CHEMPACK to the loading dock.

For *non-emergency* opening of the CHEMPACK

1. NYSDOH personnel will contact the hub hospital and make arrangements to meet with representatives from the CDC to open the CHEMPACK for service purposes that could include, but not limited to; adding, removing, exchanging or replacing pharmaceuticals, servicing the container or the sensaphone, or swapping the entire container for another.

Other incidents

1. To save assets from flood, fire or other disasters, a hub hospital should move the container(s) to a safe area within its facility, keeping security personnel with the container and immediately notifying the NYS POC to await further instructions.

APPENDIX I
Acronyms and Definitions

A

Absorption: The passing of a substance into the circulatory system of the body such as toxicants through the skin.
Aerosol: A solid particle or liquid droplet suspended in air. An aerosol is larger than a molecule and can be filtered from the air
All Hazards Response Plans: Emergency Operations plans designed to cover all areas of emergency operations, including natural disasters, terrorist attacks, disease outbreaks etc.
Atropine: An anticholinergic, with diverse effects (tachycardia, mydriasis, cycloplegia, constipation, urinary retention) attributable to reversible competitive blockage of acetylcholine at muscarinic type cholinergic receptors; used in the treatment of poisoning with organophosphate insecticides or nerve gases.

B

Biological Incident: An event in which a biological agent is used as a terrorist weapon.
Bioterrorism: The use of biological agent in a terrorist incident.
Blister Agent: A chemical agent, also called a vesicant, which causes severe blistering and burns to eyes, skin, and tissues of the respiratory tract. Exposure is through liquid or vapor contact; examples include mustard and lewisite.
Blood Agent: A chemical agent that causes asphyxiation by interfering with the ability of blood to transport oxygen. Common examples are hydrogen cyanide and cyanogens chloride.
BT: Bio-terrorism: The use of biological agent in a terrorist incident.

C

CDC: Centers for Disease Control and Prevention.
Chemical Agent: Chemical agents are solids, liquids, or gases that have chemical properties that produce lethal or serious effects in plants and animals. There are five classes of chemical agents, all of which produce incapacitation, serious injury, or death: (1) nerve agents, (2) blister agents, (3) blood agents, (4) choking agents, and (5) irritating agents.
Chemical Incident: An event in which a chemical agent is used as a terrorist weapon.
Choking Agent: A chemical agent that causes physical injury to the lungs; examples are chlorine and phosgene.
Comprehensive Emergency Management Plan:

Concept of Operations Plan (CONPLAN): The CONPLAN, developed during 1995 following PPD-39, provides overall guidance to Federal, State and local agencies concerning how the Federal government would respond to a potential or actual terrorist threat or incident that occurs in the United States.
Contingency Plan: Targets a specific issue event that arises during the course of disaster operations and presents alternative actions to respond to the situation.

D

Dermal Exposure: Exposure to toxic substances by entry through the skin.
DHS: Federal Department of Homeland Security.
DHHS: Federal Department of Health and Human Services.
DoD: Federal Department of Defense.
Division of the Strategic National Stockpile Program: The DSNS Program is designed to supplement and re-supply state and local public health agencies in the event of a biological or chemical terrorism incident anywhere, at anytime within the U.S. or its territories.
Strategic National Stockpile (SNS): The SNS is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration and airway maintenance supplies, and medical/surgical material for use in a declared biological or chemical terrorism incident.

E

Emergency: Any natural or man-caused situation that results in or may result in substantial injury or harm to the population or substantial damage to or loss of property.
EMS: Emergency Medical Services. Usually pre-hospital medical treatment provided by paramedic or ambulance services.
Exercise: A simulated emergency condition carried out for the purpose of testing and evaluating the readiness of a community or organization to handle a particular type of emergency.
Expiration Date: The last date a drug or other product should be used.

F

FDA: Federal Food and Drug Administration.

G

H

Hotspots: A term used to describe areas where the concentration of contaminants is greater than that in the surrounding areas.

I

Incidence: A measure of the number of new cases (in the form of a count or rate) of a disease or condition that occur in a specified population within a certain period.
Irritating Agent: A chemical agent, that causes respiratory distress and tearing designed to incapacitate; examples include chloropicrin, MACE, tear gas, pepper spray, and dibenzoxazepine.

J

K

Kilo: The prefix used to designate one-thousand.

L

Lethal Dose 50%: The calculated dosage of a material that would be fatal to 50% of an exposed population.
Liaison: An agency official sent to another agency to facilitate interagency communications and coordination.
Local EOP (emergency operations plan): The local EOP focuses on essential measures for protecting the public, to include warning, emergency public information, evacuation, and

shelter. To be included in a local EOP should be a mechanism for emergency responders and managers to notify and activate State resources.
Local Government: Any county, city, village, town, district, or political subdivision of any State, and Indian Tribe or authorized tribal organization, or Alaska Native village or organization, including any rural community or unincorporated town or village or any other public entity.

M

Managed Inventory:

Mitigation: Ongoing effort to lesson the impact disasters have on people and property, to moderate in force or intensity, relieve, alleviation.
Mortality: A measure of the number of people who die (in the form of a count or rate) of a disease or condition within a specified population in a certain period.
MOA: Memorandum of Agreement, a legal document whereby parties agree to specified actions and requirements.

N

Nerve Agents: Highly toxic chemical(s) that block the action of acetylcholine esterase, enzymes essential for the transmission of signals through the central nervous system. Hazardous in both liquid and vapor state, they can cause convulsions and death within minutes of exposure.
Non-liability: A federal agency or designated employee of a federal agency, including the American Red Cross (ARC) and its employees and volunteers, is not liable for any claim based upon the exercise or performance of or the failure to exercise or perform that function, (Section 305 of the Stafford Act-performing a function under the authority of P.L. 93-288).

O

P

Population at risk: Those persons who are susceptible to developing the disease being studied.
Push Packages: 12-hour Push Packages are caches of pharmaceuticals, antidotes, and medical supplies designed to address a variety of biologic or chemical agents. Push Packages are positioned in secure regional warehouses ready for immediate deployment to the airfield closest to the affected area following the federal decision to release DSNS assets.

Q

R

Recovery: Recovery includes all types of emergency actions dedicated to the continued protection of the public or to promoting the resumption of normal activities in the affected area.
Recovery Plan: A plan developed by each state, with assistance from the responding federal agencies, to restore the affected area.
Response: Those activities and programs designed to address the immediate and short-term effects of the onset of an emergency or disaster.

S

Shelf Life: The time until the expiration date of a drug or pharmaceutical
Simple Asphyxiate: An inert gas that displaces the oxygen necessary for breathing.

State: For the purpose of Federal Response Plan and as defined under P.L. 93-288, includes any state of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Trust Territory of the Pacific Islands, the Commonwealth of the Northern Mariana Islands, the Federated States of Micronesia, or the Republic of the Marshall Islands.

State Emergency Operations Plan (EOP): The state EOP is the framework within local EOPs are created and through which the federal government becomes involved. The states play three roles: (1) they assist local jurisdictions whose capabilities are overwhelmed by an emergency; (2) they themselves respond first to certain emergencies; and (3) they work with the Federal government when Federal assistance is necessary.

Strategic National Stockpile Program: The SNS Program is designed to supplement and re-supply state and local public health agencies in the event of a biological or chemical terrorism incident anywhere, at anytime within the U.S. or its territories.

Strategic National Stockpile (SNS): The SNS is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration and airway maintenance supplies, and medical/surgical material for use in a declared biological or chemical terrorism incident.

Strategic Plan: Addresses long-term issues such as impact of weather forecast, time-phased resource requirements, and problems such as permanent housing for displaced disaster victims, environmental pollution, and infrastructure restoration.

T

Terrorism: As defined by the FBI. Terrorism includes the unlawful use of force or violence against persons or property to intimidate or coerce a government, the civilian population, or any segment thereof, in the furtherance of political or social objectives.

Terrorist Incident: The FBI defines a terrorist incident as a violent act, or an act dangerous to human life, in violation of the criminal laws of the United Stated or of any state, to intimidate or coerce a government, the civilian population, or any segment there of in furtherance of political or social objectives.

Toxicity: The degree of danger posed by a substance to animal or plant life.

Toxins: Toxic substances of natural origin produced by an animal, plant, or microbe. They differ from chemical substances in that they are not manmade. Toxins may include botulism, ricin, and mycotoxins.

U

Uncertainty: The term used to describe that lack of precise knowledge in a given estimate based on the amount and quality of the evidence or data available.

V

Vesicants: Chemical agents, also called blister agents, which cause severe burns to eyes, skin, and tissues of the respiratory tract; examples include mustard agents and lewisite.

Volatilization: Entry of contaminants into the atmosphere by evaporation from soil or water.

W

Weapon of Mass Destruction (WMD): A WMD is any device, material, or substance used in a manner, in a quantity or type, under circumstances evidencing intent to cause death or serious injury to persons or significant damage to property.

Memorandum of Agreement
BETWEEN the Health Departments of Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont
For the Sharing of CHEMPACK Assets

Purpose

The CHEMPACK Project Guidelines, implemented by the CHEMPACK Project Office, Division of Strategic National Stockpile, Centers for Disease Control and Prevention, Department of Health and Human Services, provide in Section 9.3 that CHEMPACK assets may be used for mutual aid, and that states may be requested to provide mutual aid to surrounding states. The purpose of this Memorandum of Agreement (MOA) is to create a system of mutual aid between the Parties to share CHEMPACK assets. Each Party recognizes that public health emergencies transcend political jurisdictional boundaries and that intergovernmental coordination is essential for the protection of lives and for best use of available CHEMPACK assets. This MOA identifies the circumstances under which the Parties can request mutual aid, the process for requesting assistance, and the procedures and processes for facilitating such aid.

Statement of Authority

This Agreement is a Supplementary Agreement under Article VII of the Emergency Management Assistance Compact, of which all Parties are members. All Parties warrant they have the authority to execute this MOA.

Definitions for purposes of these procedures

"CHEMPACK" means the sustainable repository of nerve agent antidotes and other necessary supporting equipment to care for individuals exposed to nerve agents, including but not limited to auto-injectors, bulk symptomatic treatment supplies, and self-monitoring storage containers provided to the Parties pursuant to a Memorandum of Agreement between each Party and the Centers for Disease Control and Prevention of the United States Department of Health and Human Services. CHEMPACK is a component of the Strategic National Stockpile (SNS) Program. There are two types of CHEMPACK containers: (a) the Emergency Medical Service (EMS) container that is designed for use by emergency responders (materiel packaged primarily in auto-injectors) and (b) the Hospital container that is designed for hospital dispensing (materiel packaged primarily in multi-dose vials for precision dosing and long term care).

"CHEMPACK assets" means either the EMS container or the Hospital container described above.

"Party" or "Parties" mean the states that have entered into this agreement, specifically Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont.

Requesting CHEMPACK Assets

A. A Party may request CHEMPACK assets from another Party if the assets are needed to:
   1. Provide coverage to victims in the requesting Party's territory;
   2. Pre-position assets for the purpose of providing coverage for larger events in a neighboring; or
   3. Cooperate with cross-border exercises.

B. In addition, a Party may request that another Party temporarily store the requesting Party's CHEMPACK assets during an emergency when that emergency threatens the storage of those assets.

C. A request for CHEMPACK assets must be made to the authorized representative of a Party, as identified in Appendix A. The request may be oral or written, but a written request must be made within 5 days of making an oral request for aid.

D. The requesting Party shall include in its request for assistance:
   1. The amount and the type of assets needed;
   2. The location where the assets are needed;
   3. The location where the assets should be delivered;
   4. The representative authorized to receive the assets; and
   5. The purpose for which the request is being made.

E. The responding Party shall have exclusive authority to determine the type and amount of assets to be furnished. No Party may make any claim whatsoever against the other Party for refusal to send the requested assets.

F. If a Party agrees to provide assets, the Party shall so notify the requesting Party and provide the following information:
   1. A complete description of the CHEMPACK assets to be furnished;
   2. When and where the CHEMPACK assets shall be delivered; and
   3. The name of the person(s) to be designated as supervisory personnel.

Should a Party be unable to render assistance to a requesting Party, that Party should provide written notification to this effect to the requesting Party.

Delivery of CHEMPACK Assets

A. CHEMPACK assets, when furnished to a requesting Party, shall be delivered by the responding Party to the agreed upon location within the requesting Party's state and transferred to an authorized representative of the requesting Party, unless the parties make other specific arrangements.

B. A chain of custody shall be maintained, consistent with the Memorandum of Agreement between each Party and the Centers for Disease Control and Prevention

of the United States Department of Health and Human Services, when CHEMPACK assets are removed from a storage location in a responding Party's state, and transferred to an authorized representative of a requesting Party. The requesting Party shall likewise maintain the chain of custody until the CHEMPACK assets are appropriately used or stored.

Use of CHEMPACK Assets

In accordance with the Memorandum of Agreement between each Party and the Centers for Disease Control and Prevention of the United States Department of Health and Human Services, breaking the CHEMPACK container seal and using the packaged products is only authorized when designated state officers, employees, or agents determine that an accidental or intentional nerve agent release has threatened the medical security of the community; has put multiple lives at a risk; is beyond local emergency response capabilities; and the materiel is medically necessary to save lives.

Custody and Control

The responding Party retains custody and control of the CHEMPACK assets until transfer and delivery to the requesting Party. Upon delivery, custody and control of the CHEMPACK assets are transferred to the requesting Party.

Following this transfer of custody, should the responding Party face an emergent need for CHEMPACK assets during the period in which its assets remain with the requesting Party, the responding Party may issue an emergency request to the requesting Party to resume custody and control of the assets. Any matters regarding transportation of the assets in such a situation shall be negotiated between the two Parties.

Temporary Storage of CHEMPACK Assets

Requests for temporary storage of CHEMPACK assets, to safeguard the CHEMPACK assets during an emergency that could compromise their integrity, will be made and handled in a manner distinct from the procedures for requesting assets and costs and reimbursement in this MOA. The parties to this MOA will draft standard operating procedures to handle requests for temporary storage of CHEMPACK assets. Such standard operating procedures shall be included in each Party's emergency management plan.

Organization and Coordination

A. The Parties shall ensure that the information in Appendix A is current, with 24/7 contact information provided for the authorized representative. When information pertaining to a Party changes, that Party shall notify the other Parties as soon as is reasonably possible.

B. To the extent necessary, the Parties shall share information relating to the locations of CHEMPACK assets in their own states. Such information shall be kept confidential

to the extent required by federal and state law.

C. The Parties shall maintain a joint working group to confer at least quarterly for the purpose of reviewing and maintaining this MOA.

D. At least semiannually, the Parties shall conduct an exercise or drill to test the capabilities of this MOA.

Legal Scope/Effect

A. Nothing in this MOA is to be construed as an encroachment on the full and free exercise of U.S. federal authority, as an interference with the just supremacy of the United States, or its several states, as affecting the federal structure of the United States, or as enhancing the political power of the Party states at the expense of each other or other states.

B. This MOA is entered into pursuant to and under the authority granted by the laws of the Party states, including the Emergency Management Assistance Compact (EMAC) and any applicable federal laws. The provisions of this MOA shall be construed to conform to those laws. The Parties agree that activity pursuant to this MOA will be in accordance with all applicable current or future federal, state and local laws, rules and regulations. If any provision of this MOA violates any statute, regulation, administrative rule, or case law of a Party state or the federal government, it is considered modified to conform to that statute or rule of law.

C. This MOA addresses the relationships between and among the Parties and is intended to augment, not replace, each Party's public health emergency management plan and the established procedures governing interaction with other organizations during an emergency.

D. With its signature on this MOA, each Party agrees to cooperate with each other Party and coordinate response efforts in the event of an emergency. Each Party also agrees to incorporate the terms of this MOA into its emergency management plans.

E. Nothing herein shall be construed as committing the Parties to expend funds or involve them in any contract or other obligation for the future payment of moneys in excess of appropriations authorized by law and administratively allocated for this work.

F. Parties shall not be obligated under these procedures to send the requested assets, and the assets may be withdrawn at any time in the sole and absolute discretion of the responding Party.

G. Any notice to be given under this MOA will be in writing and will be delivered in person or by electronic facsimile, courier service, or U.S. Mail, first class or certified, return receipt requested, postage prepaid, to the authorized representative listed in

Liability

A. Officers, employees, or designees of a Party rendering aid to a requesting Party pursuant to this MOA shall be considered agents of the requesting Party for tort liability and immunity purposes. No Party or its officers or employees rendering aid in another Party state shall be liable to another Party on account of any act or omission in good faith on the part of such forces on account of maintenance or use of any equipment or supplies in connection therein. Good faith shall not include willful misconduct, gross negligence, or recklessness.

B. This MOA is by and between the Parties that have executed it. Each Party states that the MOA is intended for the mutual benefit of all Parties that have executed it and is not intended to confer any express or implied benefits on any other person, nor to confer third party beneficiary status on any person.

Dispute Resolution & Remedies Provisions

The Parties agree to good faith consultation with one another to resolve disagreements that may arise under or relating to this MOA before referring the matter to any other person or entity for settlement.

Costs and Reimbursement Provisions

Any Party rendering aid in another state pursuant to this MOA shall be reimbursed by the party receiving such aid for any loss or damage to or expense incurred in the operation of any equipment and the provision of any service in answering a request for aid and for the costs incurred in connection with such requests; provided, however, that any responding Party may assume in whole or in part such loss, damage, expense, or other cost, or may loan such equipment or donate such services to the requesting Party without charge or cost; and, provided further, that any two or more Parties may enter into supplementary agreements establishing a different allocation of costs among those Parties.

Supplementary Agreement or Party Provisions

A. Nothing in these procedures precludes any Party from entering into supplementary agreements with another Party or affects any other agreements already in force among Parties.

B. Nothing in these procedures precludes other states or local governments from becoming Parties, subject to approval of Parties to these procedures.

Amendments:

The Parties may mutually amend this MOA. Such amendments shall not be binding unless they are in writing and signed by personnel of each Party who have the delegated authority to bind each of the Parties.

Termination/Withdrawal

A. Withdrawal of any Party from this MOA is effective 30 days after written notice of intent to withdraw is sent to the other Parties.

B. The procedures set forth in this MOA shall be reviewed annually.

Effective Date

This MOA is effective upon its execution by any two Parties and is effective as to any other Party upon its execution by that Party.

Renewal

This MOA shall expire five years after its effective date, at or before which time it shall be reviewed and may be re-signed.

The persons executing this MOA on behalf of their respective entities hereby represent and warrant that they have the right, power, legal capacity, and appropriate authority to enter into this MOA on behalf of the entity that they represent.

Connecticut

Name (Print), Title

Signature

Date

Maine

Name (Print), Title

Signature

Date

Massachusetts

Name (Print), Title

Signature

Date

New Hampshire

Name (Print), Title

Signature

Date

New York

Name (Print), Title

Signature

_____

Date

Rhode Island

Name (Print), Title

Signature

_____

Date

Vermont

Name (Print), Title

Signature

_____

Date

APPENDIX A - Authorized State CHEMPACK Representatives

Connecticut:

Name	
Title/Position	
Agency/Department	
Office Phone	
Cell	
Email	
Fax	

Maine:

Name	
Title/Position	
Agency/Department	
Office Phone	
Cell	
Email	
Fax	

Massachusetts:

Name	
Title/Position	
Agency/Department	
Office Phone	
Cell	
Email	
Fax	

New Hampshire:

Name	
Title/Position	
Agency/Department	
Office Phone	
Cell	
Email	
Fax	

New York:

Name	
Title/Position	
Agency/Department	
Office Phone	
Cell	
Email	
Fax	

Rhode Island:

Name	
Title/Position	
Agency/Department	
Office Phone	
Cell	
Email	
Fax	

Vermont:

Name	
Title/Position	
Agency/Department	
Office Phone	
Cell	
Email	
Fax	

FAQ General Questions

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 federallydesignated
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 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)

Hospital Emergency Management Plan
Strategic National Stockpile Annex
CHEMPACK Appendix

1.0 Introduction

A public health emergency in Empire County or neighboring area involving exposure to a chemical nerve agent or an organophosphate-based substance would likely produce numerous casualties in urgent need of treatment. In such an event, today's limited local supply of nerve agent antidotes, in hospitals and/or with EMS units, could quickly be committed and exhausted. The Federal government has established the Centers for Disease Control and Prevention (CDC) Strategic National Stockpile (SNS) to provide urgently needed medications and supplies to the affected area. However, following a decision to deploy, the SNS may take up to 12 hours to arrive in the affected area. Treatment for nerve agent exposure must begin sooner. With this in mind, the CDC has established the SNS CHEMPACK Project to provide a sustainable, supplemental source of urgently needed nerve agent antidotes for large-casualty events by pre-positioning these items at select hospitals throughout New York State (NYS) including Empire County. In time of emergency the CHEMPACK nerve agent antidotes would be available for distribution by Empire County to additional hospitals and EMS units in the area for treatment of nerve agent or organophosphate exposure.

The CHEMPACK container is constructed of wire-lexan and is approved by the Drug Enforcement Agency for storage of Class IV controlled drugs. Each CHEMPACK contains sufficient quantities of nerve agent antidotes to respond to nerve agents such as Sarin, Soman, Tabun or VX. The contents of a CHEMPACK container will treat 1,000 casualties (hospital configured) or 454 casualties (EMS configured). The pharmaceutical materials will be monitored through the Shelf Life Extension Program (SLEP). The SLEP guidelines provide stringent quality assurance techniques needed to ensure the condition of materiel in storage are maintained in a ready-for-issue status.

While staged at locations in NYS, the CHEMPACK assets remain the property of the CDC until they are used during an emergency. The unused portion remains the property of the CDC but may no longer be part of the SLEP. The CDC SNS Program will be responsible to re-label and re-package materiel for NYS and will ensure the pharmaceuticals in the CHEMPACK containers are maintained in a ready-to-use state.

The CHEMPACK will be opened as authorized when it has been determined that an accidental or intentional nerve agent release in the region or outside of the region has threatened life beyond the capacity of the community.

2.0 Purpose

The purpose of this appendix is to provide efficient and expeditious processes for the staging of assets within the CHEMPACK Program and use of these assets in an emergency.

3.0 Scope

This appendix applies to crises or terrorism events involving chemical nerve agent or an organophosphate substance where the local or regional medical treatment capabilities are unavailable or exceeded, necessitating the use of the CHEMPACK assets. The Empire Hospital agrees to only break the CHEMPACK container seal and use package products if it is necessary to save life.

3.1 A public health crisis or terrorist event necessitating the need for CHEMPACK assets would most likely fall under one of the following two scenarios:

- A terrorist event involving a chemical nerve agent has produced numerous symptomatic casualties in immediate need of supplies in the CHEMPACK Program

- An accidental nerve agent or organophosphate exposure has threatened life and nerve agent antidotes are otherwise unavailable

3.2 This appendix will delineate hospital role responsibilities, capabilities as well as, the authority to act in the event of an activation of the CHEMPACK Program. The plan for storage of the CHEMPACK on-site, monitoring and communication notification to key hospital directors and staff in the event of activation will be outlined.

3.3 Empire Hospital personnel with the responsibility for the implementation of this appendix will receive appropriate training. Annual exercises should be coordinated with the Office of Emergency Management and the Empire County Health Department to drill specific components of the plan.

4.0 Storage

The Empire Hospital will provide a secure, environmentally controlled storage area with phone connectivity to the CDC**.** Access to the CHEMPACK storage area will be continuously monitored and controlled by Security/Pharmacy. The Empire Hospital will follow all the guidelines set forth in the NYS CHEMPACK Guidelines Handbook.

- The CHEMPACK container will be locked with a padlock. The key will be maintained in a secure manner and access by authorized staff will be 24/7

- Environmental temperature should average 68 to 77 degrees Fahrenheit. Total allowable temperature range is 58 to 86 degrees Fahrenheit.

- A current list of personnel who are authorized to access the CHEMPACK keys will be provided to the NYS Department of Health (DOH) CHEMPACK Program Point of Contact (POC) and the CDC CHEMPACK Program upon placement of the CHEMPACK and any time the list changes thereafter

5.0 Activation Notification

CHEMPACK activation should only take place if an exposure to nerve agents or an organophosphate substance occurs that exceeds the Empire Hospital's response capabilities.

5.1 In the event of an emergency not currently at Empire Hospital involving an exposure to nerve agents or an organophosphate substance requiring nerve antidote treatment, and unavailability of local supply, Empire Hospital will be notified by the Empire County Health Department/Empire County Office of Emergency Management or other predesignated hospital to open the CHEMPACK container.

- Empire Hospital will be responsible to immediately notify the key hospital directors to follow the explicit instructions for dividing the CHEMPACK package

- The Pharmacist on duty along with the Security Supervisor in charge will immediately report to the CHEMPACK storage area to open the CHEMPACK and monitor CHEMPACK product movement to the loading dock

5.2 In the event of an emergency at the Empire Hospital involving a significant number of casualties exposed to nerve agents or organophosphate material requiring nerve agent antidote treatment beyond the Empire Hospital capability, Empire Hospital will initiate the emergency management plan. The Hospital Incident Command System (HICS) will be activated.

- The Incident Commander or designee will be responsible to immediately notify the Empire County Health Department/Office of Emergency Management that the CHEMPACK container was opened and assets removed in order to sustain life

- In most cases where nerve agent antidotes from the CHEMPACK are required, the incident may exceed the capability of the Empire Hospital, therefore utilizing the HICS and communicating with the Empire County Health Department/Empire County Office of Emergency Management and

NYSDOH will help determine the scope of the event and assist in making appropriate decisions regarding the distribution of assets

6.0 Distribution

Upon receiving the authorized direction to open the CHEMPACK, the Hospital Administrator/ Incident Commander or designee will be responsible to notify the appropriate personnel (Plant Management, Pharmacy, and Security) to report to the storage area for assistance in distribution.

6.1 Security/ Plant Facilities personnel will be responsible to secure the perimeters to ensure the hallways leading to the loading dock/ED are clear of obstructions and non-authorized people.

6.2 The Empire Hospital Pharmacist or designee will be responsible to open the CHEMPACK.

- The CHEMPACK is to be divided by the authorized hospital personnel according to the instructions given by the NYSDOH, using the color-coded labeling system

- The CHEMPACK assets will be escorted at all times by the Pharmacist and Security to the designated transfer area (i.e. loading dock or ED)

- All personnel accepting control over any CHEMPACK assets will sign chain of custody receipts

- The contents of the CHEMPACK remain the property of the CDC until administered to a patient. All unused portions of the CHEMPACK are to be returned to the Empire County Hospital

- The cost of administered CHEMPACK assets cannot be charged to the victim

- The Hospital Administrator/ Incident Commander will maintain on-going communication of the status of the CHEMPACK distribution with the Empire County Health Department/Office of Emergency Management and NYSDOH

6.3 Effective March 2012 the CDC has expanded the authorized use of CHEMPACK assets to save life regardless of the number of casualties. The expanded use update recognizes:

- The commercial unavailability of certain nerve agent medical countermeasures

- Hospitals have little or no inventory of nerve agent antidotes

- Exposure to an organophosphate substance may not be a mass casualty event, but requires nerve agent antidotes to save life

6.4 When a request for CHEMPACK assets is not in response to a mass casualty event, and treatment will be occurring in the hospital emergency department, only the nerve agent antidote requested by the ED physician should be removed. In such instances removal should be in the smallest quantity possible without opening cases.

- After removal the requested nerve agent the container should be re-locked

7.0 Readiness and Response

This appendix will be routinely updated and supplemented as Federal, State and County CHEMPACK plans and procedures are developed. Contact phone numbers attached to this document will be updated on a quarterly basis.

7.1 CHEMPACK operations will be integrated into the existing incident command response structure of the Empire Hospital.

8.0 Maintenance

The Security/Pharmacist will respond immediately (within 15 minutes) to all alarm activations. They will assess the reason for the alarm and make corrections as appropriate. All alarm activations will be recorded with the actions taken documented on a log and reported to the NYSDOH.

8.1 The Empire Hospital will have the ability to correct any environmental conditions that jeopardize the assets continuing in the Shelf Life Extension Program (SLEP) within two hours or before the temperature exceeds the established limits of below 59 degrees or above 86 degrees, whichever comes first.

9.0 Contacts

Appendix M

Empire County

Comprehensive Emergency Management Plan
Terrorism Incident Annex
Strategic National Stockpile Appendix

Attachment 1: CHEMPACK

1.0 Introduction

A public health emergency in Empire County or neighboring area involving exposure to a chemical nerve agent or an organophosphate-based substance would likely produce numerous casualties in urgent need of treatment. In such an event, today's limited local supply of nerve agent antidotes, in hospitals and/or with EMS units, could quickly be committed and exhausted. The Federal government has established the Centers for Disease Control and Prevention (CDC) Strategic National Stockpile (SNS) to provide urgently needed medications and supplies to the affected area. However, following a decision to deploy, the SNS may take up to 12 hours to arrive in the affected area. Treatment for nerve agent exposure must begin sooner. With this in mind, the CDC has established the SNS CHEMPACK Project to provide a sustainable, supplemental source of urgently needed nerve agent antidotes for large-casualty events by pre-positioning these items at select hospitals throughout New York State (NYS) including Empire County. In time of emergency the CHEMPACK nerve agent antidotes would be available for distribution by Empire County to additional hospitals and EMS units in the area for treatment of nerve agent or organophosphate exposure.

2.0 Purpose

The purpose of this appendix is to identify policies and responsibilities for the management, storage, distribution and use of nerve agent antidotes in Empire County to ensure the effective use of the CHEMPACK assets.

3.0 Scope

This appendix applies to any exposure to chemical nerve agents or an organophosphate substance when local medical treatment capabilities are unavailable or exceeded, necessitating the use of CHEMPACK assets.

4.0 Situation

A public health emergency necessitating the need for CHEMPACK assets would most likely fall under one of the following two scenarios:

4.1 A terrorism event involving a chemical nerve agent has produced symptomatic casualties in immediate need of assets in the CHEMPACK container

4.2 An accidental release of an organophosphate-based material involving symptomatic casualties in immediate need of supplies in the CHEMPACK container

5.0 Assumptions

5.1 A deliberate or accidental nerve agent release can occur anywhere. Any major release would probably require additional supplies of nerve agent antidotes

5.2 The 'forward' placement of CHEMPACK assets in hospitals in Empire County will expedite delivery of antidotes to locations that require them in the event of a nerve agent emergency

5.3 The CHEMPACK distribution effort during an emergency will be the responsibility of the Empire County Office of Emergency Management

5.4 Hospital care providers may be the first to recognize the symptoms of exposure to nerve agents, and may be the first in the County to utilize CHEMPACK assets

5.5 The decision to use CHEMPACK assets should be medically driven and can be made by local medical personnel

5.6 Hospital and County emergency response officials will closely coordinate their actions to effectively distribute CHEMPACK assets

5.7 False alarms of activations of CHEMPACK assets may occur and will require communication and coordination among Federal, State, hospital and County officials

5.8 Based upon incident demands, locally staged CHEMPACK assets may be exhausted, requiring additional CHEMPACK assets from other locations outside the County

5.9 In the event that the SNS is needed to support the incident, response operations will be conducted as stated in the SNS Appendix to the Empire County Terrorism Incident Annex

6.0 Storage of CHEMPACK Containers

CHEMPACK containers are stored at hub hospital(s) in Empire County. Each container is on wheels and weighs between 500 to 700 lbs. The container dimensions are 64.5" High, 43"Wide, and 60.7"Long (Satco B style), or 60.5" High, 32.5" Wide, 60.5" Long (Satco C style). They have Lexan® Plexiglas walls lined with a hardened wire mesh to conform to FDA and the Drug Enforcement Agency (DEA) storage requirements for schedule IV controlled substances.

6.1 To extend to the maximum shelf life of CHEMPACK pharmaceuticals while stored, the Federal Shelf Life Extension Project (SLEP) will apply. SLEP requires that the antidotes remain the property of the Federal government while in storage and regulates the conditions of storage. This requires the containers be electronically monitored for security and environmental conditions.

6.2 While in storage CHEMPACK containers are equipped with a Sensaphone® 2000 monitoring device. The Sensaphone® continuously monitors the containers for intrusion, environmental conditions (temperature), and electrical power. The Sensaphone® will send an alert (by automated phone call) to Federal CHEMPACK personnel if problems are detected. The Sensaphone® validates the environmental storage of CHEMPACK supplies and does not take the place of appropriate security to be provided by the hub hospital.

6.3 The Federal CHEMPACK personnel are responsible for any re-labeling and repackaging of the CHEMPACK materiel and will ensure the pharmaceuticals are maintained in a ready-to-use state.

7.0 Agency Roles/Responsibilities/Authorities

7.1 EMPIRE COUNTY EMERGENCY MANAGEMENT

- Authorize the opening of CHEMPACK as the situation warrants.
- Receive immediate notification of the opening of CHEMPACK assets whenever authorized by another official or medical professional.
- Notify the designated transportation agency (usually law enforcement) of the opening of CHEMPACK assets and the need for security and transport.
- Notify the County Health Dept. of the opening of the CHEMPACK assets, unless the Health Dept. had already notified Emergency Management of the opening.
- Notify and coordinate other County agencies supporting the use of CHEMPACK assets.
- Notify NYS Office of Emergency Management that CHEMPACK material is accessed, distributed, or used.
- Ensure County agency personnel with key roles in the implementation of this Attachment receive initial training and annual retraining. Training containers are available from the State CHEMPACK Project.
- Test this Attachment at least annually through a table-top exercise. Functional drills may be conducted to test specific components of the Attachment.

- Participate in Joint News Center (JNC) regarding the issuance of public information on the availability of treatment.

7.2 EMPIRE COUNTY HEALTH DEPARTMENT

- Authorize the opening of CHEMPACK assets as the situation warrants.
- Receive notifications from Hub hospitals that CHEMPACK assets have been accessed.
- Notify Empire County Emergency Management and State DOH that CHEMPACK material is accessed, distributed, or used.
- Provide information on CHEMPACK distribution and medication protocols to county emergency personnel and medical personnel as requested.
- Coordinate hospital CHEMPACK training and exercising.

7.3 EMPIRE COUNTY LAW ENFORCEMENT

- Provide security and transport for CHEMPACK assets from Hub to Spoke locations.

7.4 EMPIRE COUNTY EMS COORDIANATOR

- Ensure that EMS community is familiar with CHEMPACK assets, location of assets, request process and method of transportation.

7.5 EMPIRE COUNTY REGIONAL EMERGENCY MEDICAL ADVISORY COMMITTEE (REMAC)

- Develop policies, procedures, and triage, treatment, and transportation protocols for CHEMPACK EMS assets which are consistent with the standards of the State Emergency Medical Advisory Committee and which address specific local conditions.

7.6 EMPIRE COUNTY CHEMPACK HOSPITAL STORAGE LOCATIONS (Hubs)

- Maintain CHEMPACK storage pursuant to Federal and state guidelines including routine reporting requirements**.**
- Develop and maintain a Hospital CHEMPACK Emergency Plan.
- Authorize the opening of CHEMPACK assets as the situation warrants.

- Immediately notify Empire County Department of Health that CHEMPACK material is accessed, distributed, or used. If such access is accidental or if there are SENSAPHONE false alarms, this notification should be made during normal business hours.

- Upon notification of authorization of the opening of CHEMPACK assets provide staff to assist in container opening and loading.

8.0 Concept of Operations

Empire County will direct the opening of CHEMPACK containers and use CHEMPACK assets only when it is determined that a nerve agent or organophosphate release has threatened the medical security of the community, has put life at risk, or is beyond local emergency response capabilities and it is medically necessary to save life.

9.0 Response

9.1 The distribution of CHEMPACK assets will involve numerous agencies within the County.

9.2 Within Empire County, only the following can make the determination that CHEMPACK containers may be opened and used:

- Office of Emergency Management

- Hub or Spoke Hospital Emergency Room Physicians or Medical Control Physicians

- County Commissioner of Health or designee

- County Executive

9.3 Distribution of CHEMPACK assets by Empire County will be integrated into the existing incident response organization.

9.4 Upon notification of CHEMPACK activation, the transporting agency will coordinate CHEMPACK transportation requirements.

9.5 CHEMPACK containers are stored in the following Hub hospitals in Empire County as follows:

10.0 NYSDOH Distribution Strategy for CHEMPACK Assets

10.1 The NYSDOH CHEMPACK Project relies on a “Hub-and-Spoke” system that will allow asset coverage across the County and the State. CHEMPACK assets are stored in containers at hospital(s) (“Hubs”) in Empire County. These containers are in one of two formats: Hospital containers and EMS containers. Each container is preconfigured with color-coded boxes that, when an emergency occurs, will allow the container contents to be organized into partitions that will be distributed to specified hospitals (“Spokes”) and to the incident scene in the County and in neighboring counties. Hub and Spoke locations have been pre-designated including how much CHEMPACK material they will initially receive.

10.2 The designation of Spoke hospitals and the CHEMPACK assets assigned to each is for planning purposes. During an actual event, the assets are distributed according to need. Thus, the Spoke locations and asset assignment could change.

11.0 Security CHEMPACK containers include a schedule IV controlled substance, Diazepam, which must be secured according to Drug Enforcement Agency (DEA), Food and Drug Administration (FDA), and state pharmaceutical regulations.

11.1 Controlled Substance Custody Form: Developed by NYSDOH to record the transfer of materiel from a storage location to either an emergency scene or a hospital. This form is simple, so as not to delay the delivery of the assets to an emergency scene.

- Personnel authorized to transport CHEMPACK materiel may be any person having official duties for emergency response operations, and authorized by persons in charge of any given scene
- Hospital supplies must be delivered directly to a doctor and/or a licensed pharmacist, and their signature recorded
- Copies of this form will be attached to the outside of the CHEMPACK container for easy access in the event of an emergency
- Completed forms are retained by NYSDOH for FDA review

11.2 CHEMPACK Expenditure Accounting Form: A checklist to document the amount of CHEMPACK materiel returned to a cache location following an emergency (and the amount of supplies used). This information must be reported to the NYS Department of Health.

12.0 Long-Term Dispensing Operations

Empire County officials will work with NYS officials to determine the need for extended or long term-dispensing efforts or for follow-on resupply of required medications. Resupply operations will be done through the SNS Project plans. Requests for additional SNS assets will be coordinated through the County Emergency Management Office to the State Emergency Management Office.

13.0 Planning and Plan Maintenance

This Attachment will be routinely updated and supplemented as Federal, State and County CHEMPACK plans and procedures evolve. Plan changes will be made based upon experiences and lessons-learned from drills and exercises. Contact numbers contained in this Attachment will be updated on a quarterly basis. The County Emergency Management Office coordinates plan maintenance activities.

14. Training and Exercises

County personnel with key roles in the implementation of this Attachment will receive initial training and annual retraining.

14.1 This Attachment will be tested at least annually through a table-top exercise involving key County agencies. Functional drills may be conducted to test specific components of this Attachment.

14.2 Practice EMS and/or Hospital CHEMPACK containers will be provided by NYSDOH for use in training and exercises. Practice containers (PC) will be filled with boxes that replicate both the size and weight of the actual CHEMPACK containers.

14.3 The Emergency Management Office coordinates training and exercising relative to this Attachment, with the exception of hospitals. The County Health Department will coordinate hospital training and exercising.

Dear CHEMPACK Partner,

Please review the attached announcement from the Centers for Disease Control and Prevention (CDC) regarding the expanded use of CHEMPACK assets and the availability of Atropine Sulfate and injectable diazepam.

The message from the CDC recognizes the ongoing shortage of the products listed, provides an update on current availability, and expands the allowable use of CHEMPACK assets when medically necessary to save a life.

Hospital and County planners should disseminate this very important information to all appropriate partners. Hospital and County CHEMPACK Plans should be reviewed, updated and all staff should be made aware of this change. During this process please ensure it is understood that opening a CHEMPACK container should always be a medical decision to save lives.

As a clarification to the CDC memo the NYSDOH defines a "life-saving measure" to be the treatment of a condition which if left untreated would result in immediate harm to a patient and / or the death of a patient. In essence, this expands the allowable use beyond nerve agent or organophosphate exposure.

Conditions meeting this definition which could require the use of diazepam include but are not limited to:

1) Status epilepticus
2) Intractable seizures unresponsive to other appropriate agents
3) Active seizures unresponsive to other appropriate agents
4) Organophosphate poisoning

Conditions meeting this definition which could require the use of atropine sulfate include but are not limited to:

1) Symptomatic bradycardia
2) Bradycardia with hemodynamic instability
3) Cardiac arrest
4) Organophosphate poisoning

Questions in reference to this notification should be directed to Ralph Iler or Patrick Russell at the NYSDOH Office of Health Emergency Preparedness Program. The office can be contacted at (518) 474-2893 or, ralph.iler@health.ny.gov (Iler) and patrick.russell@health.ny.gov (Russell).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention (CDC)

Memorandum

Date: 16 March 2012

To: CHEMPACK Partners

From: Vitelio Silva, CHEMPACK Lead, Logistics Branch, Division of Strategic National Stockpile

Subject: Reported Diazepam and Atropine Sulfate Shortages

Dear Colleagues:

The intent of this memorandum is to clarify procedures for accessing diazepam and atropine sulfate included in the CHEMPACK containers forward deployed across the nation. In face of the reported shortage, we have received reports that states and localities intend to access the containers in their jurisdictions to remedy immediate needs for these drugs.

Based on the 2 March 2012 report issued by the Food and Drug Administration's Drug Safety program, Atropine Sulfate is currently available from Hospira, while other manufacturers report additional deliveries this month. Injectable diazepam from Hospira is also reported to be available this month. For more information on the manufacturing status of these drugs please visit:
http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm

CHEMPACK is offering the following guidance on the usage of diazepam and atropine sulfate located in the CHEMPACK cache as a life-saving measure.

Based on the signed Memorandum of Agreement (MOA) between CDC/DSNS/CHEMPACK and unique project areas, usage of CHEMPACK countermeasures is limited to:

1. The removal of material for a life-saving measure.
2. An alternative means of procurement is not available in a timely manner to support a medical emergency.
3. Product removed and used from CHEMPACK cache cannot be charged to patient.
4. Product removed by the case(s) only. Any unused portion of product will not be returned to CHEMPACK container.

Note: Once a CHEMPACK container is opened, the program does not guarantee immediate product replacement.

Project areas should continue to adhere to agreed procedures when opening a CHEMPACK container. Once a container door is breached, CHEMPACK points of contact should expect a call from CHEMPACK staff to inquire about the security of the container and the purpose and disposition of the deployed product. For additional guidance, please contact your CHEMPACK regional representative.

Sincerely,

Vitelio Silva
CHEMPACK Lead

cc: DSNS/Logistics Branch/CHEMPACK