EMERGENCY SUPPORT FUNCTION #8
PUBLIC HEALTH
AND MEDICAL SERVICES

Tab B – CHEMPACK Plan

FACILITATING AGENCY

Ohio Department of Health
OHIO EMERGENCY OPERATIONS PLAN

CHEMPACK Plan

Tab B to ESF-8 – Public Health and Medical Services

FACILITATING AGENCY: Ohio Department of Health (ODH)

SUPPORT AGENCIES:
Ohio Emergency Management Agency (Ohio EMA)
Division of Emergency Medical Services (OEMS)
Ohio State Highway Patrol (OSHP)
Ohio Homeland Security (OHS)

I. INTRODUCTION

A. The toxic effects of nerve agents require immediate pharmaceutical intervention followed by long-term care. This pharmaceutical intervention must be supported in both the pre-hospital and hospital phase. The ability of emergency medical personnel to begin immediate treatment of individuals exposed to nerve agents will directly affect a casualty’s ability to survive the exposure. The forward placement of nerve agent antidotes under the Centers for Disease Control and Prevention’s (CDC) CHEMPACK Program will provide first responders and first receivers the resources they need to rapidly respond to large-scale nerve agent or organophosphate pesticide releases.

B. Purpose

The purpose of the CHEMPACK plan is to:

1. Clarify the responsibilities of the parties participating in the CDC’s CHEMPACK Program.

2. Provide guidance regarding the utilization and deployment of nerve agent antidotes in response to a terrorist attack or other public health emergency resulting from the release of nerve agents or organophosphate pesticides. For the purposes of this document, organophosphate pesticides are included as nerve agents.

3. The primary goal of this plan is to coordinate the efforts of support agencies in the use and management of CHEMPACK assets in response to public health and medical emergencies that require the distribution of nerve agent countermeasures.

4. The ODH maintains an internal document, the CHEMPACK Program Operational Plan, for the management of the CHEMPACK Program.
C. SCOPE

1. This plan establishes policies, procedures and organizational structures for response to a nerve agent incident requiring the use and activation of CHEMPACK counter agents.

2. Under the CHEMPACK Program, the Strategic National Stockpile (SNS) Program will:
   
a. Maintain ownership of the CHEMPACK stockpile.
   
b. Place antidotes in numerous containers under controlled and monitored storage conditions strategically-placed locations for use in the event of an incident involving nerve agents.
   
c. Implement strategies to maximize the shelf life of the antidotes to minimize re-procurement costs and maintain quality, specifically through the Federal Drug Administration’s (FDA) Shelf Life Extension Program (SLEP).

3. The CHEMPACK Program allows the Ohio Department of Health to maintain accountability and the centralized control of federal CHEMPACK caches to fulfill the criteria for the SLEP Program, while making the caches immediately available to state and local authorities.

II. SITUATION

A. General Conditions

1. The CHEMPACK Program provides for the forward placement of federally owned nerve agent antidotes in the state of Ohio.

2. Incidents necessitating countermeasures can occur with or without warning and can escalate, despite efforts to mitigate their effects.

3. The SNS Program has numerous caches of medical equipment, pharmaceuticals and vaccines in strategic locations throughout the United States. The SNS Program maintains a 12-hour response time to the states, however, this response time is inadequate in the event of a nerve agent release, when treatment must be accomplished quickly in order to save lives. Since the availability of nerve agent antidotes on emergency vehicles is limited, and hospitals maintain limited supplies of these antidotes, CHEMPACK was developed to fill this gap.

4. ODH and the support agencies to this Tab will work together to maintain program and system accountability, and the centralized control of the caches to fulfill the criteria for the SLEP Program.
5. The support agencies to this Tab have specific responsibilities as listed in the Assignment of Responsibilities, below, to manage the CHEMPACK Program and to oversee the receipt, storage, monitoring, maintenance and deployment of CHEMPACK Program assets.

III. ASSUMPTIONS

A. CHEMPACK resources will be accessible to first responders and health care personnel caring for victims of a nerve agent event. The decision to utilize these resources will be made by health care providers at the local level. In the event of an emergency, these resources can be deployed and utilized without State or Federal authorization.

B. All CHEMPACK containers are DEA-approved, and certified by the Food and Drug Administration (FDA)

IV. CONCEPT OF OPERATIONS

A. Preparedness and Prevention

1. CHEMPACK distribution throughout the State of Ohio is population-based. The containers are delivered through a coordinated effort between the CDC, ODH, and the CHEMPACK sites. CHEMPACK sites will provide ODH and CDC with contact information for individuals responsible for CHEMPACK activities, including a DEA registered pharmacist or physician, for each cache location.

2. Sustainment costs for antidote materiel is considerably less for the CDC through the Shelf Life Extension Program (SLEP) than for state and local governments. This federal program allows extension of the shelf life for selected pharmaceuticals under Food and Drug Administration (FDA) guidelines, which require ODH-designated cache sites to adhere to specific climate and security controls. The CDC will conduct annual lot testing during CHEMPACK sustainment visits to confirm the efficacy of the antidotes that are past their expiration dates.

3. No additional materiel may be added to the CHEMPACK container. However, ancillary preparedness supplies - with the exception of hazardous materials - may be stored in the area of the CHEMPACK container, provided that these items do not restrict access to, or the deployment of CHEMPACK resources, and are approved by the ODH CHEMPACK Coordinator/Designee.

4. Except where otherwise detailed, each party is responsible for its own costs. Any assistance provided by the ODH is subject to the availability of appropriations.

5. Each CHEMPACK partner in the CHEMPACK Program will be required to establish CHEMPACK protocol, as applicable for their agency. Internal and cooperative drills will be a cornerstone of CHEMPACK preparedness activities. Additionally, ODH
maintains two practice CHEMPACK containers to be used for training and exercise purposes. The practice containers contain training devices that replicate in form and function the supplies stored in the real CHEMPACKs.

B. Detection and Response

1. A declaration of emergency by the governor of Ohio is not required to use CHEMPACK contents.

2. CHEMPACK is a federal asset, and is therefore not concerned with residency in regard to deployment. Should the antidotes contained in the CHEMPACK be needed in a bordering county, district, jurisdiction, or state - that should have no bearing on the utilization decision.

3. The sole purpose of pre-positioned CHEMPACKs is to save lives. While it is desired to safeguard the location and the contents of CHEMPACK, the decision to utilize those contents is to be made as quickly as possible on the local level. No State or Federal authorization is needed.

4. The OSHP, OHS and ODH maintain a statewide listing of pre-positioned CHEMPACK containers, and will direct the response to the nearest site location and will notify that site, as well as surrounding sites, of the need (or possible need) to deploy CHEMPACK assets.

5. The assets contained within the CHEMPACK do not have to be transported within the CHEMPACK container. The container is designed to be opened so that the contents can be rapidly removed and expeditiously taken to the location where they are needed.

6. The CHEMPACK sites will make the internal decision to deploy CHEMPACK assets based upon any combination of the following:

   a. Direct observation of presenting persons exhibiting evidence of exposure.

   b. Reliable information stemming from the field presented by first responders.

   c. As directed by ODH.

7. Internally, the sites will make the decision to utilize the assets as directed by a staff physician, the Director of Pharmacy, or their designee.

8. CHEMPACK treatment supplies will be used in accordance with dosing guidance available in ODH’s CHEMPACK Program Operational Plan.

9. Transportation of CHEMPACK supplies to sites will follow the guidance set forth in reference to information contained in the CHEMPACK Program Operational Plan.
C. Deployment and Utilization

Requesting a CHEMPACK

1. Request of CHEMPACK resources will follow the guidance set forth in ODH’s CHEMPACK Program Operational Plan.

Receiving CHEMPACK Antidotes

1. When the need for a CHEMPACK is confirmed, and the nearest CHEMPACK site has been activated, the treatment site should be prepared to receive and administer the antidotes. The requesting party at a hospital should notify clinical or pharmacy personnel and/or the hospital emergency coordinator of the incoming delivery. EMS units should notify the on-scene incident commander and any EMS personnel arriving to the site of the incoming delivery.

Internal Utilization for Hospitals

1. Antidotes may be used within the ODH designated cache site if:
   a. An attending physician diagnoses nerve agent poisoning, or if the site is notified of incoming victims of a nerve agent release.
      AND
   b. The number of patients will exhaust the existing antidote cache on-hand.

2. If a CHEMPACK is opened for internal utilization, a hospital representative must notify ODH immediately.

Emergency Transfer of Custody

1. Emergency transfer of custody refers to the deployment of CHEMPACK assets from an ODH designated cache site to an emergency scene in the field or at a healthcare facility. As set forth in the CHEMPACK Program Operational Plan, only the Ohio State Highway Patrol (OSHP) will transport and transfer custody of CHEMPACK materials.

2. To maintain an appropriate chain of custody, personnel at the CHEMAPACK site should quickly complete a CHEMPACK Controlled Substance Transfer Form. The form will be used to document the transfer of materiel from an ODH designated cache site to either an emergency scene or a hospital (refer to the CHEMPACK Program Operational Plan for instructions on completing the form).

3. The form is simple to use so as not to delay the delivery of the assets to an emergency scene. One sheet is to remain at the CHEMPACK site, and one is to be sent with the materiel. Materiel going to other hospitals or clinics should be delivered to an appropriate representative. Normally, a doctor and/or a licensed pharmacist will sign
for the materials. Materiel being deployed to the field should be delivered to the incident commander or his/her chief medical officer. The responder transporting the CHEMPACK resources may be asked to stay on scene to ensure the security of the material and/or to return any unused products to the CHEMPACK site.

D. Resource Recovery and Preemptive Placement

CHEMPACK Recovery

1. The focus of the CHEMPACK Program is the mitigation of the risk of delayed treatment and subsequent loss of life through the pre-placement of nerve agent antidotes. Should these resources be utilized in response to a nerve agent event, ODH will work with the CDC to recover used resources. Once a CHEMPACK seal has been broken, the medical materiel in that container is no longer eligible for the SLEP. This factor should have no bearing on the decision to deploy or utilize the CHEMPACK antidotes in an emergency.

2. After the crisis phase has passed, the hospital POC will coordinate with the ODH POC for the return of any remaining treatment supplies. The hospital POC will maintain asset accountability and will report results to the ODH POC, who will report to the CDC POC.

3. Disposal of resulting medical waste is the responsibility of the receiving treatment facility or agency. Waste will not be returned to the cache site(s).

4. If a CHEMPACK container was inadvertently opened or damaged by a natural act, the hospital POC will inventory and report in the same manner as above. The SNS Program will not automatically replace any CHEMPACK materiel, even those used in response to an actual nerve agent event.

5. Once a CHEMPACK container is decommissioned, all remaining items obtained in the loan agreement must be returned to the CDC CHEMPACK POC.

CHEMPACK Preemptive Placement

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

   a. The ODH CHEMPACK Coordinator/Designee must be notified of the desire to relocate the container(s) at least 2 weeks prior to the preemptive movement of the CHEMPACK container. The notification must be made in writing (electronic or paper) from the cache site POC.

   b. The ODH CHEMPACK Coordinator/Designee will notify the CDC CHEMPACK Program Coordinator of the desire to relocate the container(s) at least 1 week prior to the preemptive movement of the CHEMPACK container. The notification must be made in writing (electronic or paper).
c. The ODH CHEMPACK Coordinator/Designee will notify the local CHEMPACK cache site when it is determined that the facility's container may need to be mobilized preemptively for a special event.

d. The local CHEMPACK POC will work with the ODH CHEMPACK Coordinator/Designee and CDC Program representatives to ensure that environmental and security requirements are maintained throughout transport and preemptive deployment.

e. The container will be returned to the host facility at the conclusion of the special event.

f. All non-emergency CHEMPACK movements must first be approved by ODH.

E. Training

1. The ODH CHEMPACK Coordinator/Designee will control and maintain two training containers for the purposes of training and display. These are available upon request and scheduling with ODH. The requestor will be responsible for the transportation of the training containers as needed. The requestor is responsible for wear, tear and replacement of damaged training materiel.

2. CHEMPACK training will cover the following topics:

   a. Training aids and support available.

   b. Confidentiality.

   c. Responsibilities associated with assuming custody.

   d. Receiving and further distribution of treatment supplies.

   e. Individual vials may not be relabeled with their new, extended, shelf life but they are still good regardless and will be used.

   f. Antidote dosing and administration of treatment (field, transport and hospital).

   g. Supportive care issues (ventilation, eye/skin/oral care, etc.).

   h. Returning unused treatment supplies and disposing of waste.
F. Responsibilities of the Centers for Disease Control and Prevention (CDC)

The CDC will:

1. Provide the ODH-designated cache sites with self-monitoring storage containers, which are equipped with a repository of nerve agent antidotes and other necessary and supporting products to care for individuals exposed to nerve agents, including but not limited to auto-injectors, bulk symptomatic treatments supplies.

2. Ensure proper fielding of the CHEMPACK containers at strategic ODH-designated cache sites and to validate the operational status of CHEMPACK environmental and security monitoring equipment.

3. Ensure that Schedule IV drugs are secured in a locked CHEMPACK container; that monitoring devices are operational; and that the designated person with a DEA license at the cache site has inventoried and assumed custody of the CHEMPACK.

4. Retain legal custody of all CHEMPACK materiel until or unless the CHEMPACK is used to ensure the integrity of the pharmaceuticals for SLEP.

5. Provide resources and assets necessary to sample, re-stock, re-label and dispose of CHEMPACK materials, subject to SLEP recommendations.

6. Provide resources and assets necessary to perform surveillance, quality assurance QA and quality control QC of CHEMPACK assets over the life of the program.

G. Responsibilities of ODH-Designated Cache Sites

ODH-Designated Cache Sites will:

1. Designate a point of contact (POC) and at least one alternate POC (APOC) at each CHEMPACK site. The POC will provide ODH with contact numbers at which he/she and the APOC(s) can be contacted both during normal business hours and after hours. Furthermore, each site will provide contact information for 24-hour operations.

2. Designate a pharmaceutical or medical professional with a DEA registration who will sign for and accept custody of the Schedule IV controlled substances and other pharmaceuticals in CHEMPACK containers for each ODH designated cache site. That person will be responsible for the storage and safeguarding of the container(s) in the facility and ensure compliance with applicable local, State and Federal regulatory guidelines. Notwithstanding that, CDC will retain ownership of the CHEMPACK materiel and will ensure the integrity of the pharmaceuticals in accordance with SLEP recommendations/ requirements.

3. Notify the ODH CHEMPACK Coordinator/Designee of any changes in contact personnel within one business day of assignment of a new POC and/or new APOC(s).
4. Maintain the CHEMPACK container(s) at the originally designated ODH designated cache site(s), unless ODH and CDC consent to a relocation, or unless an emergency requires the medical assets within the container(s).

5. Ensure the CHEMPACK containers remain intact and sealed until and unless they are needed for utilization.

6. Break the CHEMPACK container seal and make use of the packaged products when it has been determined that an accidental or intentional nerve agent release has threatened the public health of the community, has put multiple lives at risk, is beyond existing emergency response capabilities, and the CHEMPACK materiel is medically necessary to save lives.

7. Correct non-compliant environmental conditions within one hour of notification. If conditions cannot be corrected, the CHEMPACK POC will coordinate with the CDC CHEMPACK Logistics Team and ODH personnel to take any-and-all precautionary measures to safeguard the quality or security of the materiel.

8. Conduct monthly security checks to ensure the pharmaceuticals are secure. A visual inspection of the cage and seal will suffice; the CHEMPACK container should not be opened to inspect the contents. If a breach of security is suspected, the site will contact ODH immediately for further instruction.

V. ASSIGNMENTS OF RESPONSIBILITY

A. Ohio Department of Health (ODH)

1. Manage the CHEMPACK Program and oversee the receipt, storage, monitoring, maintenance and deployment of CHEMPACK Program assets.

2. Ensure that the ODH designated cache site location meets CDC guidance respective to size, lighting, ventilation, temperature, sanitation, humidity, space and security.

3. Authorize any non-emergency movement of CHEMPACK resources, including pre-positioning assets for special events and permanent relocation within the ODH designated cache site, or permanent relocation to outside facilities.

4. Coordinate communications with the CDC and ODH designated cache sites for the completion of any sustainment operations.

5. Assist the Division of Emergency Medical Services (OEMS) in the development of educational materials to enhance the recognition of nerve agent events and awareness of available CHEMPACK resources among first responders and healthcare personnel.
B. Ohio Emergency Management Agency (Ohio EMA)
   1. Maintain situation awareness of the deployment of CHEMPACK assets through the Ohio Watch Office.

C. Division of Emergency Medical Services (OEMS)
   1. Assist in the development, instruction, and distribution of educational materials to enhance the recognition of nerve agent events and awareness of available CHEMPACK resources among first responders and healthcare personnel.
   2. Develop, and as needed, revise statewide treatment protocols for Emergency Medical Systems and hospitals.

D. Ohio State Highway Patrol (OSHP)
   1. Provide the transportation and security for the movement of CHEMPACK resources from the host cache site to first responders and healthcare personnel as set forth in the CHEMPACK Program Operational Plan.
   2. Receive the initial call for activation and begin the notification of activation per the CHEMPACK Program Operational Plan.
   3. Provide OSHP dispatch and posts with the proper training and exercises for CHEMPACK plans and procedures.
   4. In the event of a CHEMPACK activation, notify the host hospital of all known information about the incident, particularly size and locale upon initial call-up.

E. Ohio Homeland Security (OHS)
   1. Maintain the OHS Communication and Information Management System (CIMS) 24/7/365 Points of Contact roster and site location of all CHEMPACK assets.
   2. Annually, test and update all emergency CHEMPACK POC contact numbers.

VI. PLAN MAINTENANCE

A. A review and update of the Ohio CHEMPACK Plan will be accomplished annually by all state agencies identified within the plan to address plan deficiencies that are revealed during exercises or operations and to sustain the plan as an operational component of the State EOP.

B. Ohio EMA will facilitate annual Ohio CHEMPACK Plan reviews and updates of this plan.