



## **Vaccine Storage and Handling Questions and Answers**

Prepared by the Immunization Healthcare Division (IHD)

[www.health.mil/coldchain](http://www.health.mil/coldchain)

877-GET-VACC

[DoDVaccines@mail.mil](mailto:DoDVaccines@mail.mil)

*Last Updated: 15 July 2019*

Vaccine and Diluent Storage .....	1
General Information.....	1
Vaccine Storage Equipment .....	2
Temperature Monitoring .....	3
Vaccine and Diluent Storage Practices.....	7
Vaccine Handling .....	10
Vaccine Inventory Management.....	10
Vaccine Preparation and Disposal.....	11
Emergency Response Recommendations .....	13
Vaccine Packing and Transport .....	15

# Vaccine and Diluent Storage

## General Information

### **1. What is Cold Chain Management (CCM)?**

The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal condition. The cold chain begins at the manufacturer, continues through shipment to medical logistics, then to the vaccination site, and ends at administration of the vaccine to the patient.

### **2. What happens to vaccines when they are not properly stored?**

Failure to adhere to recommended specifications for storage and handling of vaccines may reduce potency, resulting in inadequate immune response in the recipient and inadequate protection against disease. Excessive heat or cold exposure damages vaccine. Each time vaccine is exposed to excessive heat or cold, the loss of potency increases and eventually, if the cold chain is not correctly maintained, all potency will be lost, and the vaccine becomes useless.

### **3. What policy and processes should be developed for the proper CCM of vaccines?**

All DoD activities that maintain and administer vaccines will incorporate three elements into their policies and processes for proper CCM: a well-trained and competent staff, reliable storage and temperature monitoring equipment, and accurate vaccine inventory management. The policy will define vaccine transportation, delivery, storage, handling and monitoring requirements, training and required actions to be taken in the event of a compromised storage environment. DoD activities will have clearly written, detailed, and up-to-date routine and emergency response SOPs to serve as a reference and training tool, for all locations that handle and store vaccine.

### **4. What storage and handling training should locations that store vaccines implement?**

DoD activities will establish a formal CCM orientation training and competency program for newly assigned personnel that includes all routine and emergency storage and handling procedures for their location. Additionally, all personnel who store, handle, and/or administer vaccines will receive annual refresher training on CCM principles and procedures, and training whenever new vaccines

are added to inventory or whenever recommendations for storage and handling of vaccines are updated.

#### **5. Who should receive storage and handling training?**

DoD activities will ensure all staff members (e.g., logistic, immunization, inpatient, ancillary, temporary, etc.) are properly trained on CCM procedures. Personnel receiving training will include anyone who delivers or receives shipments and/or has access to areas where vaccines are stored and/or administered. Only trained and qualified personnel, working within their scope of practice, are eligible to transport, store, and handle vaccines.

### **Vaccine Storage Equipment**

#### **1. What are the general requirements for the type of refrigerator, freezer, or combined refrigerator/freezer unit used to store vaccines? Is there a DoD policy requiring certain vaccine storage equipment to be purchased?**

Storage units must be suitable for vaccine storage, capable of maintaining required temperature range year-round, and have space to accommodate maximum inventory without crowding. Pharmaceutical grade stand-alone refrigerator(s) and freezer(s) are recommended for storage of vaccines. Stand-alone units can vary in size from compact, under-the-counter (not dormitory) style to large, stand-alone, pharmaceutical grade units. If a household-grade, combination refrigerator/frost-free freezer unit is used, only use the refrigerator compartment for storing vaccines. Use a separate stand-alone freezer to store frozen vaccines. In addition, frost-free or automatic defrost cycle units are preferred.

#### **2. Should the freezer compartment of a house-hold combination unit be turned off if not in use?**

No. If you turn off the freezer portion of a combination refrigerator/freezer, the refrigerated compartment will not maintain the proper temperature.

#### **3. When is a “dormitory-style” refrigerator considered adequate for vaccine storage?**

Never! Dormitory- or bar-style refrigerator/freezer units are not authorized for any vaccine storage. A "dormitory-style" refrigerator is a small combination refrigerator/freezer unit that is outfitted with one exterior door and an evaporator

plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. Dormitory-style units pose a significant risk of freezing vaccines even when used only for temporary storage. During testing, dormitory-style refrigerators demonstrated consistently unacceptable performance, regardless of where the vaccine was placed inside the unit. This type of unit has severe temperature control and stability issues.

#### **4. What steps can be taken to prevent accidental loss of power to storage units?**

Post highly visible “DO NOT UNPLUG” signs at outlets and on each storage units. Where feasible, label circuit breaker fuses to alert personnel not to turn off the power and include information on who to contact if the power to the storage units will be turned off due to construction or other electrical work. Plug vaccine storage units directly into the wall outlet. Do not plug into outlets that can be activated by a wall switch or outlets with built in circuit switches (may have a reset button). Do not use extension cords, multi-outlet power strips or surge protectors. Secure the storage unit plug to the electrical outlet by using a safety-lock plug, an outlet cover, or a cover outlet with a cage. Connect the vaccine storage units to a red emergency outlet or backup power generator to ensure proper storage conditions are maintained during commercial power interruption.

#### **5. What are the requirements for the vaccine storage room?**

Place storage unit(s) in a well-ventilated room at temperatures between 20° C and 25° C /68° F and 77° F, leaving space between the unit, ceiling, and any wall in accordance with the storage unit user manual to ensure proper heat exchange and cooling functions. If the room temperature is too hot, it is recommended that a small portable air-conditioning unit or extra ventilation vents are added to ensure room temperature remains stable and does not cause the refrigerator and/or freezer temperatures to shift outside of the recommended range.

## **Temperature Monitoring**

#### **1. What are the required refrigerator vs. freezer temperatures?**

Store vaccine correctly within the temperature parameters outlined in the manufacturer’s package insert. Store refrigerated vaccines at temperatures between 2°C and 8°/36°F and 46°F. Set the refrigerator thermostat midrange to achieve a temperature of about 5°C/40°F. Do not expose refrigerated vaccines to

freezing temperatures. Store frozen vaccines at temperatures between -50°C and -15°/-58°F and +5°F.

**2. What type of thermometer is best for measuring temperatures in a vaccine storage unit?**

Every vaccine storage unit must have a temperature-monitoring device, and investing in a reliable device is less expensive than replacing vaccines wasted due to inaccurate temperature readings. The Centers for Disease Control and Prevention (CDC) recommends the use of a continuous monitoring and recording digital data logger (DDL) with a current and valid Certificate of Calibration Testing (also known as a Report of Calibration) set at a minimum recording interval of at least every 30 minutes.

Unlike a simple minimum/maximum thermometer, which only shows the warmest and coldest temperatures reached in a unit, DDLs provide detailed information on all temperatures recorded at a preset interval. DDLs provide the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a temperature excursion). The temperature data is stored in the DDL's memory, and may be downloaded and viewed on a computer.

**3. What characteristics should be included in a digital data logger?**

Digital data loggers should include the following characteristics: a detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®); an alarm for out-of-range temperatures; low battery indicator; current, minimum, and maximum temperature display; and logging interval that can be programmed by the user to measure and record temperatures no less frequently than every 30 minutes.

**4. Why does the thermometer probe need to be suspended in glycol? Won't it work just as well if it is measuring air temperature?**

Glycol-encased probes provide a more accurate reading of actual vaccine vial temperatures when placed in the same area where the vaccine is stored. Vaccines are more thermostable than air because they are fluid-filled and thus have a larger thermal mass. Standard probes that measure air temperature can fluctuate with the defrost cycles of the unit, frequent opening and closing the door on busy workdays, air circulation patterns, etc. This could lead someone to inaccurately interpret changes in air temperature to mean that the vaccine temperature was out of range.

**5. What type of thermometers should NOT be used for measuring temperatures in a vaccine storage unit?**

Thermometers that are NOT recommended for monitoring vaccine temperatures are uncertified fluid-filled biosafe liquid thermometers, bi-metal stem thermometers, food thermometers, household mercury thermometers, and infrared (sometimes called laser or non-contact) thermometers. These types of thermometers can be difficult to read and only indicate the temperature at the precise time they are read. Although chart recorders are not routinely recommended, these paper-based loggers may be the only option for continuous temperature monitoring in facilities that do not have access to a computer.

**6. Where within the vaccine storage unit should the thermometer be placed?**

Place the buffered probe of the temperature monitoring device (TMD) in the center of the unit in close proximity to the vaccines being stored. Refer to the TMDs owner's manual for instructions on proper TMD placement. Proper placement is very important since it helps the staff to most accurately identify the actual vaccine vial temperatures and to take appropriate corrective actions quickly if necessary. If using a digital data logger (DDL), place the DDL's active digital display on the outside of the storage unit so temperatures can be checked without opening the door and disturbing the probe.

**7. How often should temperatures be recorded for refrigerator and freezers storing vaccines on the temperature log?**

Physically check and record storage unit minimum and maximum temperatures at the start of each workday. The minimum/maximum temperatures recorded should be those obtained since the last workday when the minimum/maximum temperatures were reset. If the temperature monitoring device used does not display minimum/maximum temperatures, then check and record the current temperature a minimum of two times (at the start and end of the workday). These twice-daily physical checks should be done even if there is an electronic monitoring system installed. Vaccine outside of a refrigerator or freezer must have the temperature checked and documented every hour.

Storage areas with restricted access should have a device installed (light indicator/audible alarm) indicating when the storage unit temperature is out of range that can be checked without physically entering the restricted area.

**8. Do twice daily physical temperature checks need to occur if a data logger and/or alarm system is in place?**

Yes. DHA-IHD still recommends documenting twice-daily temperature checks even with a continuous data logger and/or alarm system because twice-daily checks will give you a better indication of any problem with your storage unit's function. Physically checking the storage unit temperatures at the end of the duty day provides staff an opportunity to confirm that the storage unit doors are closed and that the storage units are functioning properly (plugged in). DHA-IHD has received reports of temperature excursions due to unplugged storage units, tripped circuit breakers, or opened storage unit doors. Many of these temperature excursions occurred during normal duty hours but the staff did not discover them until after hours, when alerted by the alarm system, or the next duty day, primarily because the alarm system did not alert them (e.g., not programmed correctly or backup battery failed). Incorporating an end-of-day process for physically checking the storage unit temperatures, and not relying solely on an electronic monitoring system, will help with the early detection and response to out-of-range temperatures. Additionally, confirm that current personnel contact information exists on auto-dialers, and that appropriate coverage occurs during periods of leave, holidays, and weekends.

**9. How should vaccines be stored over a weekend or holiday if staff is not available?**

For locations without backup power and the ability to monitor temperatures remotely 24 hours a day/7 days a week, implement procedures to minimize on-hand material and return remaining vaccine to a properly monitored and alarmed storage location at the end of each duty day. Activities must incorporate a temperature monitoring device that is capable of recording temperatures so that verification of nightly storage temperatures can be reviewed at the start of each workday to ensure the proper temperature range was maintained, preventing the administration of potentially non-viable or compromised vaccine.

**10. Who should adjust the temperature of a vaccine storage unit?**

Only the primary or backup vaccine coordinator should adjust the temperature of the storage unit. Limiting access to the thermostat reduces the risk of improperly adjusting the temperatures and exposing vaccines to temperatures that are too warm or too cold. Post a warning sign on the storage unit with contact information for the primary and backup vaccine coordinator.

**11. How long should the temperature in a new refrigerator be monitored before storing vaccines in it?**

In a newly installed or repaired refrigerator or freezer, start by setting the empty refrigerator thermostat at 5°C/40°F and the empty freezer thermostat at -



15°C/5°F or colder. It may take 2 to 7 days to stabilize the refrigerator temperature and 2 to 3 days for the freezer temperature. When the storage unit temperature is stable at the recommended range for a minimum of 24 hours, place the vaccines into the unit.

**12. How can you stabilize temperatures in the refrigerator and freezer?**

You can help stabilize and maintain the temperatures by placing water bottles on the top shelf and floor and in the door racks of the refrigerator unit and place water bottles against the walls, in the back, on the floor, and in the door racks of the freezer unit. Putting water in the storage units can help stabilize temperatures that can be destabilized by frequently opening and closing unit doors or a power failure. Place water bottles carefully so they cannot dislodge, preventing the door from closing securely or weighing the door down so the seals are not tight. Label all water bottles, “Do Not Drink.”

**13. Why should the temperature of the room where the vaccine storage unit is located be recorded?**

Documenting the ambient room temperature is important because if the storage unit should lose power or fail, often the only temperature to base the temperature excursion on is the room temperature. Additionally, since some diluents are to be stored at room temperature, considered to be between 20°-25°C/68°-77°F, recording the ambient room temperature will ensure they are at the proper temperature range.

**14. How long do we need to keep our refrigerator/freezer temperature tracking logs?**

Temperature logs should be kept for 3 years or per Service/local policy. Archived temperature logs can show how well the vaccine storage unit is working overtime and can be used to determine when a unit may need adjustment, maintenance, or replacement, such as when temperatures are consistently at the limit or sometimes beyond the limit of the recommended temperature range.

## Vaccine and Diluent Storage Practices

- 1. There is a vent in our household-grade combination refrigerator/freezer that brings in cold air from the freezer. Vaccines stored near this vent are colder to the touch. Could this be a problem?**

Yes. Vaccines that are stored in the refrigerator portion of a combination refrigerator/freezer should be moved away from the vent located in the refrigerator compartment. The cold air from the freezer is circulated into the refrigerator compartment to cool it, which can cause your vaccines to freeze.

**2. Is the top shelf of a pharmacy-grade storage unit acceptable for vaccine storage if there is a fan directly above it?**

Generally speaking, it is recommended to avoid the top shelf and the areas near vents due to temperature fluctuations. However, most pharmaceutical-grade units have more uniform temperatures than household units under normal operating conditions. During a power outage, the top shelf is an area of caution for all units as the temperatures increase most quickly there. In this instance, it would be best to check with the manufacturer to see if the top shelf is appropriate for storage in your unit.

**3. Can you store vaccine in the vegetable bins or if the bins have been removed, in the space occupied by the bins?**

Vaccines should not be stored in vegetable bins or the space occupied by vegetable bins. This area is commonly closer to the motor of the unit and the temperature is different from that in the body of the refrigerator. We recommend that you remove the vegetable bins and put bottles of water in that space to help maintain a constant temperature in your refrigerator.

**4. Can we store vaccine in the same unit where we store employees' lunches?**

No, biologics should never be stored with food or drinks.

**5. Is it okay to store lab specimens, blood products and/or other biologics in the same unit as vaccines?**

Refrigerators and freezers used for vaccine storage must be dedicated for storage of vaccines only. If other medications and biological products must be stored in the same unit as vaccines, always store them below the vaccines and on a different shelf. This prevents contamination of the vaccines should the other products spill and reduces the likelihood of medication errors.

**6. How should vaccines be stored in the refrigerator and/or freezer?**

Place vaccine in the center of the storage unit, contained in original packaging, inside a designated storage container and positioned 2 to 3 inches from storage unit walls so air can circulate around the vaccines. Do not place vaccine in storage unit doors or on the top shelf of the refrigerator if the cooling vent from

the freezer opens there. If the top shelf of the refrigerator must be used for vaccine storage, it would be best to place MMR on this shelf because MMR is not sensitive to freezing temperatures.

Arrange vaccines in rows or use trays, uncovered containers, or perforated bins, allowing space between rows to promote air circulation. Do not pack the storage unit too tightly. This can restrict air circulation and impact vaccine temperature. Place vaccines and diluents with the earliest expiration dates in the front of those with later expiration dates.

**7. Why should containers and bins be used to store vaccines in the storage unit?**

DHA-IHD recommends the use of bins, baskets, or some other type of uncovered containers that allow for organization and air circulation for vaccines and diluents within the storage unit. Storage in containers or bins can help maintain temperature longer, especially if power is lost.

**8. How should vaccines be labeled in the refrigerator and freezer?**

Attach labels to shelves and containers to identify where each type of vaccine or diluent is stored. Include additional information such as age indications, gender or other information unique to the vaccine on the label. Store vaccines with similar packaging or names, or with both pediatric and adult formulations, on different shelves to minimize the risk of administration errors. Make sure to label the formulation “pediatric” or “adult,” if applicable. Color code the labels (e.g., one color for pediatric and one for adult vaccines). Prevent the storage of vaccines that sound or look alike next to each other, like DTaP and Tdap.

**9. Do vaccines need to be protected from light?**

Yes. Human papillomavirus (HPV), Haemophilus influenzae type B (Hib), inactivated polio (IPV), Japanese encephalitis (JEV), meningococcal, measles-mumps-rubella (MMR), measles-mumps-rubella-varicella (MMRV), rabies, rotavirus, varicella, zoster, and some influenza vaccines are sensitive to light, causing loss of potency, so must be protected from light at all times. Store these vaccines at the appropriate temperatures in their boxes with the tops on until they are needed.

**10. Can the vaccine be removed from its packaging to store more products in the refrigerator?**

No. Storing loose vaccine vials outside of their boxes is not recommended. Keep vaccines in their original packaging with the lids on until ready for administration.

Do not store loose vials or manufacturer-filled syringes outside of their packaging. This practice makes it more difficult to track expiration dates and manage inventory, increases the risk of administration errors, and exposes vaccine to light (check package insert for vaccine light sensitivity information).

#### **11. Where is the appropriate place to store diluents?**

Store diluent correctly within the temperature parameters outlined in the manufacturer's package insert. Some diluents must be refrigerated, while others may be stored in the refrigerator or at room temperature (no warmer than 25°C/77°F). Whenever possible, store diluent next to corresponding vaccine. ACAM2000 diluent is shipped refrigerated with vaccine but should be stored at room temperature.

## **Vaccine Handling**

### **Vaccine Inventory Management**

#### **1. How often should I conduct a vaccine and diluent inventory?**

Conduct a vaccine and diluent inventory at a minimum monthly to ensure adequate supplies are on hand to meet demand. Ensure vaccines are stored in original packaging. Place rubber bands around boxes of like lot numbers to alert staff to a change in vaccine lot number. Rotate stock so that vaccines and diluents with the soonest expiration dates are moved to the front and are used first to avoid waste due to expiration. Check vaccine and diluent expiration dates a minimum of weekly to remove expired items from usable stock.

#### **2. When the expiration date of a vaccine indicates a month and year, does the vaccine expire on the first or last day of the month?**

When the expiration date is marked with only a month and year, the vaccine or diluent may be used up to and including the last day of the month indicated on the vial. Any unused vaccine or diluent should not be used after this month has passed. If the expiration date printed on all vaccines and diluent vials and boxes includes the month/day/year the vaccine or diluent may be used up to and including this date. Monitor and rotate your vaccine supply carefully so that vaccines do not expire.

#### **3. What are the guidelines regarding use of multi-dose vaccine vials?**

An opened multi-dose vial (MDV) of vaccine that has been stored and handled properly and is normal in appearance can be used through the expiration date printed on the vial unless there is a “beyond use date” (BUD) noted in the package insert. The BUD is the date or time after which an opened MDV cannot be used. For example, inactivated polio vaccine in a multi-dose vial can be used through the expiration date on the vial. For some vaccines, the manufacturer specifies that once the multi-dose vial has been entered or the rubber stopper punctured, the vaccine must be used within a certain number of days. This is the case for some inactivated influenza vaccines that indicate once the stopper of the multi-dose vial has been pierced, the vial must be discarded within 28 days. Vaccines in multi-dose vials that require reconstitution can be used through the expiration date printed on the label as long as the vaccine is not contaminated, or unless indicated otherwise by the manufacturer. Any vaccine not used within the BUD should be discarded. Specific information regarding the BUD can be found in the vaccine package inserts, which can be found at <https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Preventable-Diseases/Package-Inserts>.

- 4. Is it acceptable to write the expiration date (the “Beyond Use Date”) of an opened vaccine multi-dose vial on the box rather than the vial or must it be written on the vial?**

It is acceptable to put the Beyond Use Date (BUD) on the packaging; this may help when reviewing inventory. But a provider should always read the label on the vial before administering a vaccine. It is possible for a vial to be placed in the wrong box. So the vial label is the safest place to put the BUD. Vial labels are small and it may require putting an extra sticky label on the vial.

## Vaccine Preparation and Disposal

- 1. How long can manufacturer-filled syringes be stored once the rubber tip cap is removed and the needle is attached?**

When manufacturer-filled glass syringes are not supplied with needles, the needles should be attached just before administration. If a needle is attached to a sealed manufacturer prefilled syringe, the syringe should be used or discarded at the end of the clinic day because the sterile seal has been broken.

- 2. How long is a vaccine viable if it has been stored in the refrigerator in a syringe?**

Disposable syringes are meant for administration of vaccines, not for storage. The CDC recommends vaccines that have been drawn into syringes by the provider be discarded at the end of the clinic day. Manufacturer-filled syringes that have not been activated (i.e., have not had the needle guard removed or a needle attached) may be kept and used until their expiration date.

**3. Are vaccine diluents interchangeable?**

No. Diluents are not interchangeable, even diluents from the same manufacturer. Therefore, use only the specific diluent provided by the manufacturer for each type of vaccine to ensure adequate potency and safety of the resulting mixture.

**4. What information should be marked on the multi-dose vaccine vial once it has been opened?**

Mark a multi-dose vial with the date it was first opened and mark reconstituted vaccine with the date and time it was reconstituted. This is important for two reasons: Some vaccines expire within a certain time after opening or after reconstitution. This may not be the same as the expiration date; and dating opened or reconstituted vials helps manage vaccine inventory by identifying which vials should be used first.

**5. Can you pre-fill syringes prior to mass influenza vaccination clinic?**

Vaccine manufacturers do not recommend pre-drawing vaccines in advance of large immunization events because no data exist on the stability of vaccines stored in general-use syringes that have been filled by end-users. If vaccine must be pre-drawn (e.g., during a flu drive, deployment line): Do not draw up vaccines before arriving at the immunization event – drawing up doses days or even hours before is not acceptable and each person administering vaccines should draw up no more than one multi-dose vial, or 10 doses, at a time. Any remaining vaccine drawn up in syringes and not administered, must be discarded at the end of the duty day and reported as a loss.

**6. How long can a reconstituted multi-dose vial be used once it is opened and a dose is withdrawn?**

The expiration date for reconstituted multi-dose vials varies from product to product and the new expiration date and time will differ from that printed on the vial. For example, after reconstitution, MMR vaccine must be administered within 8 hours and must be kept at refrigerator temperature during this time. Consult the package insert for the most up-to-date information about expiration dates and

times following reconstitution. Unused reconstituted vaccines kept beyond these limits should not be administered.

**7. Some manufacturers' package inserts state that a vaccine should be used immediately after reconstitution. In the context of reconstitution and administration of vaccines, how is "immediately" defined?**

There are various requirements for the use of vaccines after reconstitution. Some manufacturers' package inserts require that the vaccine be used or discarded in varying time frames ranging from 24 hours after reconstitution to immediately after reconstitution. While the specific timeframes are simple to interpret, there can be some confusion as to what the requirement of "immediately" actually means. The CDC considers "immediately" to be the reasonable time it takes to prepare and transport the vaccine to the patient to be administered. This would include any limited documentation that may be related to this process. It is up to the judgment of a provider to determine if a vaccine has not been used in the appropriate time. Some manufacturers have indicated to providers that "immediately" can be up to 30 minutes. The definition of "immediately" varies from manufacturer to manufacturer. Some do not have the data to put forth a general timeframe as to what "immediately" means. The CDC recommends that the provider contact the manufacturer any time there is a question about whether the vaccine has not been used in the appropriate timeframe.

**8. How should I dispose of expired and/or compromised vaccines?**

First and foremost, rotate your vaccine supply so expensive vaccine does not expire in your refrigerator. If you discover expired vaccine, remove it from the refrigerator or freezer so that it is not inadvertently given to a patient. Expired vaccines and diluents should NEVER be administered, even if it is only 1 day past the expiration date. Whenever possible, unused single-dose vials, multi-dose vials, and manufacturer-filled syringes of vaccine and diluent (expired and/or compromised) may be returnable for credit by using a pharmaceutical reverse distributor program. Using this program provides a safe option for managing unused or expired vaccines while maintaining full compliance with regulating agencies. Contact your site's pharmacy or logistics office for guidance on the use of this program.

## **Emergency Response Recommendations**

**1. What is a "temperature excursion"?**

Any temperature reading outside the recommended range for vaccine storage is a temperature excursion. However, it is the total amount of time, or cumulative time, out of range that affects the viability of vaccine. Any time appropriate vaccine storage temperatures are in question, contact your Immunization Healthcare Specialist (IHS), Defense Logistics Agency-Troop Support Medical (DLA-TSM), and/or the U.S. Army Medical Materiel Agency Distribution Operations Center (USAMMA-DOC) for further guidance about whether or not a vaccine may be used. Above all, don't chart an out-of-range temperature and not act on it! DHA-IHD has created temperature recording logs and a troubleshooting record to document unacceptable vaccine storage events. These materials provide guidance on the appropriate steps to take in the event of a storage problem.

## **2. What are the appropriate steps if a vaccine compromise is suspected?**

If vaccine is suspected to have been outside the recommended temperature range, the vaccine coordinator, supervisor, or if necessary, the person who discovered the problem should begin to document the event. Record the time and temperature of the storage unit when the power goes out, when the power is restored, and when the thermometer reading is back within the recommended range. Do not leave vaccine in a nonfunctioning storage unit. Immediately move the vaccine to a working storage unit at proper temperature. Label potentially compromised vaccine as "Do Not Use" and place it in a separate container apart from other products in the storage unit. Do not destroy, discard or use the vaccine until released from USAMMA-DOC and or DLA-TSM. The most current information for reporting a suspected vaccine compromise can be found at [www.health.mil/coldchain](http://www.health.mil/coldchain).

## **3. What is an Emergency Vaccine Retrieval and Storage Plan?**

The Emergency Vaccine Retrieval and Storage Plan provides up-to-date information regarding procedures to follow to protect and/or retrieve vaccines as quickly as possible when a potentially compromising situation occurs such as inclement weather conditions, natural disasters, or other emergencies that might disrupt power or flood any office where vaccine is stored. The immunization clinic vaccine coordinator should develop an Emergency Vaccine Retrieval and Storage Plan and keep it in a prominent and easily accessible location near the vaccine storage units.

## **4. Why is it important to identify an alternate storage location?**

In case of an emergency situation, having an established working agreement with at least one alternate storage facility with a backup generator where vaccine



can be appropriately stored and monitored for the interim, can save thousands of dollars in vaccines.

Ensure that advanced arrangements are made with the facility(s) to store your vaccine when weather predictions call for inclement conditions (e.g., tornadoes, hurricanes, ice, severe snowstorms), when your vaccine storage equipment cannot be repaired, or when the power cannot be restored before the vaccine storage unit temperature rises above the recommended range.

**5. What steps should be taken if the vaccine storage unit malfunctions?**

Move the vaccine to a properly functioning storage unit with internal temperatures within the recommended ranges, then attempt to troubleshoot the problem. Do not allow the vaccine to remain in a nonfunctioning unit for an extended period of time while you attempt to resolve the problem. If you are unsure how long the storage unit will not be functioning properly or you determine that the problem cannot be corrected in time to maintain the internal temperature within the recommended range, activate your clinic's Emergency Vaccine Retrieval and Storage Plan.

**6. If a refrigerator records a temperature of 32°F or below but the vaccine does not appear frozen, can it still be used?**

No. If you find that a vaccine has been exposed to an inappropriate temperature, determine the reason for the temperature alteration, mark the vaccine "Do Not Use," and contact USAMMA-DOC and/or DLA-TSM to determine if the vaccine is still viable.

## Vaccine Packing and Transport

**1. Can vaccines be transported in a paper bag?**

No, you must use a hard-sided or Styrofoam™ insulated cooler with at least 2-inch thick walls, or other approved mobile transport container capable of maintaining the required storage temperatures of 2°-8°C/36°-46°F with appropriate packing material and thermometer.

**2. How should storage containers be labeled when transporting vaccines offsite?**

Attach labels to the outside of the container to clearly identify the contents as being valuable and fragile vaccines. Record vaccine type(s), quantity, date, time, and originating facility on a label on the outside of the container. Document the vaccine storage unit temperature at the time the vaccine is removed for transport.

**3. What type of storage containers should be used when administering immunizations offsite?**

You must use validated storage containers and packing protocols which assures product safety and efficacy. You may use hard-sided or Styrofoam™ insulated coolers with at least 2-inch thick walls, or other approved mobile transport container capable of maintaining the required storage temperatures of 2°-8°C/36°-46°F. Thin-walled Styrofoam™ coolers, such as those purchased at grocery stores to hold beverages, are not acceptable. The containers should remain closed as much as possible, only the amount of vaccine needed at one time should be removed for preparation and administration, always include calibrated temperature-monitoring device to track temperatures during transport and storage, and the temperature inside the container should be read and documented at least hourly.

**4. Where can additional vaccine storage and handling information be found?**

The IHD website has a [webpage](#) dedicated to vaccine storage and handling, which includes tools and products to help you build quality storage and handling practices. The CDC also has a [vaccine storage and handling webpage](#) that includes numerous resources including forms, checklists, posters, and guidelines on proper vaccine storage and handling.