

PFIZER 12 YEARS & OLDER -90°C VACCINE STORAGE AND HANDLING COMPETENCY ASSESSMENT

Note: Stability data on the Pfizer product will continue to be evaluated even after the vaccine begins shipping. Staff should be aware information may be updated and staff should stay abreast of any change in vaccine handling. The competency form will be updated as needed.

This document is used exclusively to evaluate healthcare personnel giving immunizations at DoD facilities or associated field activities.

Employee Name: _____ Assessment Start Date: _____ Completion Date: _____

Required Competency or Skill	Self Assessment	Evaluation Method	Competency Validated by Supervisor (Signature & date)	Comments/Additional Resources
1. Training and Equipment	<i>Demonstrate and recognize training and safety equipment to allow for personnel safety when handling dry ice and the proper equipment needed to store ultra-cold vaccine.</i>			
1.1 Watch the Pfizer handling video for the storage and handling of the Pfizer 12 yrs & older COVID-19 vaccine. https://www.cvdvaccine-us.com/product-storage-and-dry-ice				
1.2 Demonstrate the proper wearing of dry ice protective equipment; safety goggles and thermal gloves (designed to handle dry ice) that allow manual dexterity. All exposed skin must be protected from dry ice exposure.				
1.3 Review the Material Safety Data Sheet (MSDS) for the dry ice pellets and the precautions regarding skin contact, asphyxiation hazard and over-pressurization hazard when working with dry ice.				
1.4 Identify the MTF Vaccine Coordinator and the location of the ultra-cold freezer(s) designated for Pfizer 12 yrs & older COVID-19 vaccines. Vaccine Coordinator: _____ Freezer Location: _____ DHA – IHS: _____ USAMMA-DOC Call line: 301-619-3017/4318 or usarmy.detrick.medcom-usamma.mbx.doc@army.mil				
2. Opening -90°C Pfizer Vaccine Shipping Container	<i>Apply all procedures for safely opening shipping container, transferring vaccine without a temperature excursion and disposition procedures to return the shipping container and GPS.</i>			
2.1 STOP: Before opening the thermal shipping container, make sure the area in which you are working has <u>proper ventilation</u> . Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, <u>can result in depletion of oxygen, resulting in asphyxiation</u> . The dry ice will vaporize into CO2 and can quickly displace O2 in confined space, causing dizziness, headaches, difficulty breathing, loss of consciousness and death.				
2.2 Upon receipt, open the top flap of the box and disable the GPS enabled logger by pressing the “STOP” button on the device. Open the inner lid holding data logger (lid should remain attached to box). If product is indicating a temperature alarm, continue to proceed with				

Self-Assessment

1= Experienced 2=Needs Practice 3= Never Done N/A=Not Applicable

Evaluation/Validation Methodologies:

T = Tests D = Demonstration/Observation V = Verbal I = Interactive Class

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storage protocols and mark vaccine in freezer with “DO NOT USE”. Once vaccine is stored at proper temperatures, follow DHA guidelines for reporting potential shipment temperature compromise.				
2.3 STOP: Put on protective equipment (at minimum safety glasses and thermal gloves) to protect skin against dry ice exposure.				
2.4 Carefully remove the dry ice pod from the shipper and put to the side.				
<p>2.5 Take out the payload box and remove the vial trays, inspect for broken vaccine vials and immediately transfer to proper storage. Dry ice gloves do not need to be used when removing vial tray or vials, recommend use of routine nitrile gloves. Transfer of product from the shipper must be done within 5 minutes to prevent premature product thawing. Each shipping box may contain 1-5 vaccine trays.</p> <p>a. <u>Purple vial capped vaccine</u> can be placed in Ultra-Cold freezer (-90°C to -60°C) for 9 months; Freezer (-25°C to -15°C) for 2 weeks; or Refrigerator (2°C to 8°C) for 1 month.</p> <p>b. <u>Gray vial capped vaccine</u> can be placed in Ultra-Cold freezer (-90°C to -60°C) for 6 months or Refrigerator (2°C to 8°C) for 10 weeks.</p>				
2.6 Shipping box should be visually inspected to make sure all vaccine trays have been removed.				
2.7 STOP: Put on protective equipment (at minimum safety glasses and thermal gloves) to protect skin against dry ice exposure. Replace dry ice pod in box.				
2.8 STOP: Sublimating (vaporizing to a gas) of dry ice must occur in <u>well-ventilated area</u> . Do NOT leave box to sublimate in a confined space to include walk in coolers, refrigerators, freezers, closets or vehicles. Do NOT dispose of dry ice in a sink, toilet or other drain. Do NOT dispose of dry ice in trash or garbage. Due to risk of explosion do NOT store dry ice in ultra-low freezers. Do NOT leave dry ice unattended in open areas.				
2.9 Shipping container and temperature data logger will be returned within 10 business days and no later than 20 days after receipt, per the protocol annotated inside the box lid.				
3. Storing Pfizer Vaccine in -90°C Ultra-cold Freezer, -25°C to -15°C Freezer or 2°C to 8°C Refrigerator	<i>Operate storage equipment and apply proper procedures for storing the vaccine in a -90°C to -60°C ultra-cold freezer, -25°C to -15°C freezer or 2°C to 8°C refrigerator to protect against a temperature compromise.</i>			

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<p>3.1 Prior to moving vaccine to ultra-cold freezer, regular freezer or refrigerator, confirm the freezer is clearly labeled as “Ultra-Cold -90°C to -60°C”, “Freezer -25°C to -15°C” or “Refrigerator 2°C to 8°C” and “For COVID-19 Vaccine Storage”. Visually confirm refrigerator or freezer has capacity to store vials before beginning vaccine transfer.</p> <p>a. <u>Purple vial capped vaccine</u> can be placed in Ultra-Cold freezer (-90°C to -60°C) for 9 months; Freezer (-25°C to -15°C) for 2 weeks; or Refrigerator (2°C to 8°C) for 1 month.</p> <p>b. <u>Gray vial capped vaccine</u> can be placed in Ultra-Cold freezer (-90°C to -60°C) for 6 months or Refrigerator (2°C to 8°C) for 10 weeks.</p>				
<p>3.2 If possible vaccine should be stored in the shipping tray. Vaccine trays may be stacked in the refrigerator or freezer. During storage minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.</p>				
<p>3.3 Vaccine will not be stored in an ultra-cold freezer containing human tissue samples. Vaccine may be stored in a refrigerator and/or freezer containing blood and other bodily fluid specimens but the vaccine must be stored <u>above</u> blood/bodily fluids.</p>				
<p>3.4 Vaccine may be stored in ultra-cold freezer at -90°C to -60°C until the expiry date printed on the label. Trays should be marked with date placed in storage and the date the vaccine will expire (9 months for <u>purple vial caps</u> and 6 months for <u>gray caps</u>).</p>				
<p>3.5 <u>Purple vial capped vaccine</u> may be stored at -25°C to -15°C for up to <u>2 weeks</u>. Trays should be marked with date placed in storage and the date the vaccine will expire (2 weeks after placed in regular freezer). Vials stored at -25°C to -15°C may be returned <u>one-time</u> to the ultra-cold storage condition of -90°C to -60°C. Total cumulative time the vials are stored at -25°C to -15°C will be tracked and should not exceed 2 weeks.</p>				
<p>3.6 <u>Purple vial capped vaccine</u> may be stored in the refrigerator at 2°C to 8°C for up to 1 month and <u>gray vial capped vaccine</u> for 10 weeks. Trays should be marked with the date placed in the refrigerator and the date the vaccine will expire. Do not refreeze thawed vials.</p>				
<p>3.6 Vaccine not used before expiration will be marked as expired, segregated from viable vaccine and reported as waste per DHA MedLog protocol.</p>				

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4. Storing the Pfizer Vaccine in the 195-pack Thermal Shipping Containers with Dry Ice	<i>Demonstrate the proper procedures for re-icing of the 195-pack thermal shipping container to prevent a vaccine temperature compromise and to safely handle dry ice. Distinguish the storage limitations when vaccine is stored in the shipping container.</i>			
<p>4.1 Locations without an ultra-cold freezer may store vaccine in the 195-pack thermal shipping container only under very strict guidelines:</p> <p>a. Within 24 hours of receipt and after opening the container, it must be replenished with up to 20kg of dry ice pellets.</p> <p>b. With each re-icing the 195-pack thermal container can maintain ultra-low temperature storage for 5 days with up to 2 box openings per day at no more than 3 minutes at a time.</p> <p>c. If more frequent openings are necessary, more frequent ice replenishments will be required. Replenish dry ice in the 195-pack thermal shipping container at the end of business on days when the vaccination site will be closed the following day, such as weekends or holidays.</p> <p>d. The 195-pack thermal shipping container can be re-iced allowing a total of 30 days of storage. (1st re-ice within 24 hours and re-ice every 5 days).</p> <p>e. The container may be stored up to 30 days if stored at an ambient room temperature of 59 - 77° Fahrenheit.</p> <p>f. A visible label must be placed on the outside box flap indicating when the vaccine started its 30 days of temporary storage in the shipping container and when it will expire if not moved to a -80°C freezer.</p>				
<p>4.2 STOP: When using the 195-pack thermal shipping container for temporary storage it must have an ultra-cold temperature monitor. The ultra-cold temperature monitor shipped from the manufacturer may not be used for continued monitoring on-site. The monitor probe must be placed in the location of the vial trays within the payload area.</p>				
<p>4.3 Each time the box is opened it must be closed within 3 minute and be taped shut each time it is closed. Box should not be opened more than twice per day.</p>				
<p>4.4 STOP: Before opening the 195-pack thermal shipping container</p>				

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<p>for re-icing, make sure the area in which you are working has proper ventilation.</p> <p>a. STOP: Put protective equipment (safety glasses and thermal gloves) on to protect skin against dry ice exposure before beginning dry ice replenishing.</p> <p>b. Open the thermal shipping container by cutting the tape on the outside of the box and gently open the lid using the cutout in the foam lid. While wearing protective equipment remove the dry ice pod.</p> <p>c. Fill and low areas in the side compartments of the thermal shipping container with dry ice pellets until completely filled, so that it is equal with but does not exceed the top edges of the side compartments.</p> <p>d. Reinsert the dry ice pod into the aluminum lining cavity, which holds the vial cartons. Then fill the dry ice pod to the top with dry ice (do not overfill).</p> <p>e. Close the foam lid and the thermal shipping container lid and reseal with tape. To maintain required temperatures, it is critical that the container lid is flush and properly taped shut.</p>				
<p>4.5 After 30 days, any vaccine that has not been used may be moved to a refrigerator. Purple vial capped vaccine for up to 1 month and gray vial capped vaccine for up to 10 weeks. Do not refreeze thawed vials.</p>				
<p>4.6 Refrigerated vaccine not used within the specified time period will be marked as expired, segregated from viable vaccine and reported as waste per DHA MedLog protocol.</p>				
<p>5. Thawing Vaccine in Preparation for Administration</p>	<i>Apply the proper procedures to safely thaw vaccine in preparation for vaccine administration to a recipient.</i>			
<p>5.1 Vaccine removed from freezer may thaw in the refrigerator. Purple vial capped vaccine can be stored in the refrigerator for 1 month and gray vial capped vaccine for up to 10 weeks. A carton of 10 vials may take up to 6 hours to thaw. If needed for immediate use, a vial will defrost at <u>room temperature in 30 min</u>. Thawed vials may be handled in room light conditions. Once vials are thawed they should not be refrozen.</p>				
<p>5.2 Store the purple cap and grey cap vaccines in a separate marked bin specific for the COVID-19 vaccine. Bin labels at https://www.health.mil/coldchain</p>				

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<p>5.3 Prior to dilution, <u>purple vial capped vaccine</u> may remain at room temperature (up to 25C/77F) for a total of 2 hours (including any thaw time). After dilution, the vial should be held between 2°C to 25°C. Vials should be discarded 6 hours after first puncture.</p> <p>Prior to first puncture, <u>gray vial capped vaccine</u> may remain at room temperature (up to 25C/77F) for a total of 12 hours. After first puncture, the vial should be held between 2°C to 25°C. Vials should be discarded 12 hours after first puncture.</p>				
<p>5.4 <u>Purple vial capped vaccine</u> not used within 6 hours and <u>gray vial capped vaccine</u> not used within 12 hours must be marked as expired, segregated from viable vaccine and reported as waste per DHA MedLog protocol.</p>				
<p>6. Transportation of Frozen or Thawed Vials</p>		<p><i>Apply the proper procedures to safely transport frozen or thawed vaccine to alternate vaccination sites.</i></p>		
<p>6.1 Transport of Frozen Vials: If local redistribution is needed and full cartons containing vials cannot be transported in ultra-cold frozen state:</p> <p>a. <u>Purple vial capped vaccine</u> maybe transported frozen at -25°C to -15°C. Any hours used for transport at -25°C to -15°C count against the 2 week limit for storage at -25°C to -15°C. Frozen purple vial capped vaccine may be returned one-time to the ultra-cold storage condition of -90°C to -60°C.</p> <p>b. <u>Gray vial capped vaccine</u> may be transported frozen at -90°C to -60°C.</p>				
<p>6.2 Transport of Thawed Vials:</p> <p>a. <u>Purple vial capped vaccine</u> maybe transported refrigerated at 2°C to 8°C. Any hours used for transport at 2°C to 8°C count against the 1 month limit for storage at 2°C to 8°C. Once vials are thawed they should not be refrozen.</p> <p>b. <u>Gray vial capped vaccine</u> may be transported refrigerated at 2°C to 8°C. Any hours used for transport at 2°C to 8°C count against the 10 week limit for storage at 2°C to 8°C. Once vials are thawed they should not be refrozen.</p>				

I understand that of all the topics listed, I will be allowed to perform only those for my skill level/scope of practice and only after I have successfully demonstrated competency.

Employee Signature: _____ Date: _____

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Annual Review

Date	Competency Review Validated (Supervisor Signature)	Comments
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