

# PFIZER -80 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
<b>1. Training and Equipment</b>				
<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 COVID-19 vaccine. <a href="https://www.cvdvaccine-us.com/product-storage-and-dry-ice">https://www.cvdvaccine-us.com/product-storage-and-dry-ice</a>				
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 COVID-19 vaccines. Vaccine Coordinator: _____ Freezer Location: _____ DHA – IHS: _____ USAMMA-DOC Call line: 301-619-3017/4318 or <a href="mailto:usarmy.detrick.medcom-usamma.mbx.doc@mail.mil">usarmy.detrick.medcom-usamma.mbx.doc@mail.mil</a>				
<b>2. Opening -80°C Pfizer Vaccine Shipping Container</b>				
<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 <b>STOP:</b> 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 storage protocols and mark vaccine in freezer with “DO NOT USE”.				

**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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Once vaccine is stored at proper temperatures, follow DHA guidelines for reporting potential shipment temperature compromise.				
<b>2.3 STOP:</b> Put on protective equipment (at minimum safety glasses and thermal gloves) to protect skin against dry ice exposure.				
<b>2.4</b> Carefully remove the dry ice pod from the shipper and put to the side.				
<b>2.5</b> Take out the payload box and remove the vial trays, inspect for broken vaccine vials and immediately transfer to an ultra-cold freezer. 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.				
<b>2.6</b> Shipping box should be visually inspected to make sure all vaccine trays have been removed.				
<b>2.7 STOP:</b> Put on protective equipment (at minimum safety glasses and thermal gloves) to protect skin against dry ice exposure. Replace dry ice pod in box.				
<b>2.8 STOP:</b> 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.				
<b>2.9</b> 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.				
<b>3. Storing the Pfizer Vaccine in a -80°C Vaccine Ultra-cold Freezer or at -25°C to -15°C Freezer</b>	<i>Operate storage equipment and apply proper procedures for storing the vaccine in a -80°C to -60°C ultra-cold freezer or -25°C to -15°C freezer to protect against a temperature compromise.</i>			
<b>3.1</b> Prior to moving vaccine to ultra-cold freezer or regular freezer, confirm the freezer is clearly labeled as “Ultra-Cold -80°C to -60°C” or “Freezer -25°C to -15°C” and “For COVID-19 Vaccine Storage”. Visually confirm freezer has capacity to store vials before beginning vaccine transfer.				
<b>3.2</b> If possible vaccine should be stored in the shipping tray. Vaccine trays may be stacked in the freezer. During storage minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.				
<b>3.3</b> Vaccine will not be stored in an ultra-cold freezer containing				

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human tissue samples. Vaccine may be stored in a freezer containing blood and other bodily fluid specimens but the vaccine must be stored <u>above</u> blood/bodily fluids.				
3.4 Vaccine may be stored in ultra-cold freezer at -80°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 (6 months after placed in freezer).				
3.5 Vaccine 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 recommended storage condition of -80°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.				
3.6 Frozen vaccine not used before expiration will be marked as expired, segregated from viable vaccine and reported as waste per DHA MedLog protocol.				
<b>4. Storing the Pfizer Vaccine in the Thermal Shipping Containers with Dry Ice</b>	<i>Demonstrate the proper procedures for re-icing of the 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 thermal shipping container under very strict guidelines:</p> <p>a. Within 24 hours of receipt and after opening the container, it must be replenished with up to 23kg of dry ice pellets.</p> <p>b. With each re-icing the container can maintain ultra-low temperature storage for 5 days with up to 2 box openings at no more than 1 minute each per day.</p> <p>c. The container can be re-iced up to <u>3 times</u> allowing a total of 15 days of storage in the shipping container. (1<sup>st</sup> re-ice within 24 hours, 2<sup>nd</sup> re-ice 5 days later, 3<sup>rd</sup> re-ice 5 days after the 2<sup>nd</sup> re-ice).</p> <p>d. The container may be stored up to 15 days if stored at an ambient room temperature of 59 - 77° Fahrenheit.</p> <p>e. A visible label must be placed on the outside box flap indicating when the vaccine started its 15 days of temporary storage in the</p>				

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shipping container and when it will expire if not moved to a -80°C freezer.				
<p><b>4.2 STOP:</b> When using the 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><b>4.3</b> 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><b>4.4 STOP:</b> Before opening the thermal shipping container for re-icing, make sure the area in which you are working has proper ventilation.</p> <p><b>a. STOP:</b> Put protective equipment (safety glasses and thermal gloves) on to protect skin against dry ice exposure before beginning dry ice replenishing. While wearing protective equipment remove the dry ice pod.</p> <p><b>b.</b> Fill the sides of the container with dry ice until there is a thin layer of dry ice on top of the product carton.</p> <p><b>c.</b> Reinsert the dry ice pod and fill it with dry ice, leaving space between dry ice sleeve and the sides of the shipper.</p> <p><b>d.</b> Close the lid, close the outer container and reseal with tape.</p>				
<p><b>4.5</b> If after 15 days, any vaccine that has not been used may be moved to a refrigerator for up to <u>5 additional days (120 hours)</u>.</p>				
<p><b>4.6</b> Refrigerated vaccine not used within the 5 days will be marked as expired, segregated from viable vaccine and reported as waste per DHA MedLog protocol.</p>				
<p><b>5. Storing the Pfizer Vaccine in the Refrigerator at 2-8°C</b></p>	<p><i>Demonstrate appropriate use of storage equipment and the proper procedures for storing vaccine in a refrigerator, in order to protect against a temperature compromise. Explain the vaccine expiration limits when stored at 2-8°C.</i></p>			
<p><b>5.1</b> Prior to moving the vaccine into refrigerated storage, confirm the refrigerator is clearly labeled as “Refrigerator 2-8°C” and “For COVID-19 Vaccine Storage”. Visually confirm refrigerator has capacity to store vials before beginning vaccine transfer.</p>				

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<p><b>5.2 STOP:</b> Before opening the thermal shipping container make sure the area in which you are working has proper ventilation.</p> <p><b>STOP:</b> Put protective equipment (safety glasses and thermal gloves) on to protect skin against dry ice exposure. Remove the payload box.</p>				
<p><b>5.3</b> Immediately transfer vial trays from the payload box to the refrigerator. Thermal gloves do not need to be used to remove trays or vials from the payload box.</p>				
<p><b>5.4</b> Trays will be marked with Beyond Use Date of 5 days (120 hours) after vaccine is placed in the refrigerator.</p>				
<p><b>5.5 STOP:</b> Move shipping container to <u>well ventilated</u> area to allow for sublimation of dry ice. Do not leave dry ice unattended. See notes in <u>section 2.8</u>.</p>				
<p><b>5.6</b> Refrigerated vaccine not used within the 5 days will be marked as expired, segregated from viable vaccine and reported as waste per DHA MedLog protocol.</p>				
<p><b>6. Thawing Vaccine in Preparation for Administration</b></p>		<p><i>Apply the proper procedures to safely thaw vaccine in preparation for vaccine administration to a recipient.</i></p>		
<p><b>6.1</b> Vaccine removed from freezer may thaw <u>in the refrigerator for 3 hours</u> (this is for an entire tray, 195 vials, smaller amounts may defrost faster) or 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.</p>				
<p><b>6.2</b> Vaccine may remain at room temperature for up to 2 hours total. It must be returned to the refrigerator if not used within the 2 hours.</p>				
<p><b>6.3</b> Vaccine left out beyond the 2 hours must be marked as expired, segregated from viable vaccine and reported as waste per DHA MedLog protocol.</p>				
<p><b>7. Transportation of Frozen or Thawed Vials</b></p>		<p><i>Apply the proper procedures to safely transport frozen or thawed vaccine to alternate vaccination sites.</i></p>		
<p><b>7.1 Transport of Frozen Vials:</b> If local redistribution is needed and full cartons containing vials cannot be transported in ultra-cold frozen state, vials may be 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 vials transported may be returned one time to the recommended storage condition of -80°C to -60°C.</p>				
<p><b>7.2 Transport of Thawed Vials:</b> One or more thawed vials may be transported refrigerated, at 2-8°C, for up to 12 hours. Any hours used for transport count against the 120 hour limit for storage of the vaccine at 2-8°C.</p>				

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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: \_\_\_\_\_

**Annual Review**

Date	Competency Review Validated (Supervisor Signature)	Comments
_____	_____	_____
_____	_____	_____
_____	_____	_____

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