COVID-19 Vaccine Storage and Handling Guidance and Vaccine Management Plan (VMP)

Virginia Department of Health, Division of Immunization

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Section One: Introduction

Vaccines must be stored and handled properly in order to prevent and eradicate vaccinepreventable diseases. Failure to properly store and handle vaccines results in financial loss, revaccination, and reduced public confidence in vaccines. Vaccines that have been exposed to improper conditions have reduced potency, resulting in inadequate immune response and poor

protection against disease.

The temperature-controlled environment used to maintain and transport vaccines in optimal condition is called the **vaccine cold chain**. The cold chain begins with the storage unit at the manufacturing plant, extends to the transport and delivery of vaccine and storage at a clinic, and ends with administration of the vaccine to a patient.

Every time a vaccine is exposed to improper conditions (e.g., overexposure to heat, cold, or light), its potency is reduced. If a refrigerated vaccine is exposed to freezing temperature just once, its potency can be destroyed.

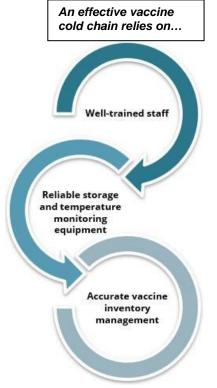
This document is designed to assist providers in properly storing and handling federal COVID-19 vaccines as part of the Virginia Department of Health, Division of Immunization COVID-19 Vaccination Program. It is a modified version of the Centers for Disease Control and Prevention (CDC) Storage and Handling Toolkit, which you are highly recommended to

review in order to fully understand the breadth of information, recommendations, and resources available to assist you in properly storing and handling your vaccine supply.

Always refer to the manufacturer information and package inserts or contact the manufacturer directly for detailed storage and handling protocols for individual vaccines.

The Virginia Department of Health are not authorized to assess, validate, verify, or endorse products or services of private companies. When purchasing storage and handling equipment, keep in mind that products labeled as "CDC-compliant" have not been reviewed by the CDC or the Virginia Department of Health.

Always contact the Virginia Division of Immunization if you are unsure if a specific product meets requirements.



Section Two: Staff and Training

Clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs) will help your facility stay organized, serve as a reference and training tool, and assure proper vaccine management. SOPs should be maintained near vaccine storage units where staff can find them. Additionally, well-trained staff are necessary for implementing SOPs at the facility. Staff should be trained on storage and handling procedures as part of new employee orientation, annually, whenever new vaccines are added to the inventory, and whenever storage and handling recommendations change.

At a minimum, SOPs should contain plans and information for three major areas:

- General: contact information for vaccine manufacturers, equipment service providers, and important facility staff; job descriptions; regularly used forms; and staff training requirements
- 2) Vaccine inventory management: ordering vaccines, monitoring storage, etc.
- 3) **Emergency:** steps to take in the event of equipment malfunctions, power failures, or other emergencies that can compromise storage conditions

A **primary vaccine coordinator** should be designated for ensuring all vaccines are stored and handled correctly. A **back-up vaccine coordinator** should also be appointed to act in the absence of the primary coordinator. Both coordinators should be responsible for:

- Ordering vaccine (once available) and overseeing receipt/storage of deliveries
- Maintaining all documentation, such as vaccine inventory and temperature logs
- Monitoring operation of vaccine storage equipment and systems
- Organizing vaccines in storage units, including rotating stock at least weekly so vaccines with earlier expiration dates are used first and removing expired vaccines
- Monitoring temperature data on storage units, including:
 - Setting up temperature monitoring devices (TMDs)
 - Checking minimum/maximum temperatures for the last 24 hours in the morning and checking current temperatures in the morning and afternoon
 - Reviewing temperature data weekly for shifts in temperature trends
 - Responding to and reporting temperature excursions
- Organizing vaccine-related training and ensuring staff complete training
- Overseeing vaccine transport when necessary
- Overseeing emergency procedures, such as tracking inclement weather conditions and ensuring appropriate handling of vaccines during a disaster or power outage

Completion of CDC's COVID-19 Vaccine Training Modules for all primary and back-up coordinators at all sites enrolled in the COVID-19 Vaccination Program is required. Pharmacists signing the Storage and Handling portion of the COVID-19 Provider Agreement are also required to complete the training modules. Continuing Education Units (CEUs) are available upon completion of each module.

Current training modules are listed below and may be found on <u>CDC's COVID-19 Vaccine</u> Training Modules Homepage.

- COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers
- Janssen COVID-19 Vaccine (Johnson & Johnson): What Healthcare Professionals Need to Know
- Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know
- Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know

Section Three: Equipment

Vaccine Storage Unit Recommendations

Purpose-built or pharmaceutical grade units are designed specifically for storing biologics such as vaccines. These units:

- Can be compact, under-the-counter style or large
- Often have microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistant temperature detector [RTD], or thermistor)
- Often have fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of- range temperature

Household grade units can be an acceptable alternative under the right conditions. When using these units, the freezer compartment of a combination unit should never be used to store vaccines, and certain areas of the refrigerated compartment should be avoided as well. Separate standalone freezers are necessary for storing frozen vaccine.

If a **manual defrost freezer** is used, an appropriate back-up freezer must be available to store vaccine in when the main freezer is being defrosted. A defrost plan should be included in the storage and handling SOPs, and the unit should be defrosted when the unit has accumulated to a thickness of approximately 1 cm.

Dormitory-style and bar-style units may **never** be used to store vaccine. These units have a single external door and evaporator plate (cooling coil) that is usually located in the "freezer"

within the refrigerator. These units place vaccine at high risk of freezing.

Storage Unit Placement

Vaccine temperature stability requires air circulation around the outside of the storage unit. Recommendations for where to place refrigerators and freezers include:

- Unit should be in well-ventilated room with standard room temperatures (between 20°C and 25°C [68°F and 77°F]) and space between the unit, ceiling, and walls
- Nothing should block the cover of the motor compartment
- Unit should be firm and level, with bottom of unit above floor
- Door should be able to open and close smoothly and fit squarely against unit body

Stabilizing Temperatures in New and Repaired Units

Prior to storing vaccines in a new or repaired unit, check and record the minimum and maximum temperatures each workday for two to seven days. Once you have **two consecutive days** of temperatures within the recommended range, the unit is stable and can be used for vaccine storage.

Recommended Temperature Ranges

Different COVID-19 vaccines have different recommended temperature ranges.

Refrigerated vaccines should be stored in refrigerators maintained at temperatures between 2°C and 8°C. **Frozen vaccines** should be stored in freezers maintained at temperatures between -25°C and -15°C. **Ultra-cold vaccines** should be stored in freezers or dry ice shipping container in which product is received between -95°C and -60°C.

Temperature Monitoring Devices (TMD)

All storage units must be equipped with a specific type of TMD known as a digital data logger (DDL). DDLs provide details on all temperatures the unit has reached at preset intervals. DDLs should have the following features:

- Detachable, buffered probe (or digitally buffered device that mimics buffered probe)
- Alarms (audible or visual) for out-of-range temperatures, with parameters set as:
 - Refrigerator low alarm (too cold) set to trigger after 15 consecutive minutes or longer below 2.0°C
 - Refrigerator high alarm (too warm) set to trigger after 60 consecutive minutes or longer above 8.0°C
 - Freezer high alarm (too warm) set to trigger after 60 consecutive minutes or longer above -15°C
- · Low-battery indicator
- Active display outside of unit that allows current, minimum, and maximum

temperatures to be monitored without opening unit door

- Recommended uncertainty of +/- 0.5°C
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes
- Ability to easily download data for review
- Ability to report temperatures in Celsius
- A current and valid Certificate of Calibration

A back-up DDL with a valid and current Certificate of Calibration must also be available on-site and readily available in case a primary DDL malfunctions or requires re- calibration. The back-up DDL should be stored outside of the storage unit until needed, and it should have a different calibration re-testing date than the primary DDLs so that one may be used while the other is being replaced or sent out for re-calibration.

Certificate of Calibration Testing

Calibration testing ensures the accuracy of DDLs against nationally accepted standards.

Calibration testing should be done every one or two years or according to the manufacturer's suggested timeline. Certificates of Calibration testing should indicate one or more of the following about the testing:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
- Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Manual Recognition Arrangement (MRA) signatory body
- Traceable to standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F or higher
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Certificates of Calibration Testing should also include:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument is in tolerance)
- Recommended uncertainty of +/- 0.5°C (+/- 1°F) or less

The following TMDs should not be used

- Alcohol or mercury thermometers
- Bimetal stem TMDs
- · TMDs used for food
- Chart recorded
- Infrared TMDs
- TMDs that do not have a current and valid Certificate of Calibration testing

Temperature Probe Placement

The DDL probe should be placed in the middle area of the storage unit with the vaccines. Anchoring the probe will prevent it from being moved. It should **not** be placed in the doors, near or against the walls, close to vents, or on the floor of the unit as temperatures in these locations may differ significantly from the temperature in the zone where vaccine is stored.

Monitoring Vaccine Temperature and Equipment

Daily Checks

Current temperatures should be reviewed for each storage unit **twice a day** (once in the morning and once in the afternoon). During the morning temperature check, the minimum and maximum temperature for the past 24 hours should also be reviewed. Temperature logs are available on the <u>VDH Website</u>.

Weekly Checks

DDL reports must be printed, reviewed, and signed by the Vaccine Coordinator each week and maintained with temperature logs for three years.

Power Supply

The following precautions must be taken to protect the unit's power supply:

- Plug in only one unit per electrical outlet to avoid creating a fire hazard or triggering a safety switch that turns the power off
- Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged
- Post "DO NOT UNPLUG" signs at outlets and on units
- Post "DO NOT TURN OFF" signs on fuses and circuit breakers
- Use caution when using power outlets that can be tripped or switched off and avoid using built-in circuit switches which may have reset buttons, outlets that can be activated by a wall switch, and multi-outlet power strips
 - If built-in current switches or power strip surge protection must be used, make sure the power strip is rated to carry the maximum current as specified by the manufacturer of the refrigerator or freezer.

Organizing and Storing Vaccine

Store vaccines in their original packaging with lids closed until ready for administration. Loose vials or syringes may be exposed to unnecessary light and may be more difficult to track for expiration dates. Not storing vaccines in the original packaging affects inventory management and increases the risk of administration errors. Best practices for correct storage of vaccines within a refrigerator or freezer include:

- Store each type of vaccine/diluent in original packaging and in a separate container
- Position vaccines/diluents 2-3 inches from unit walls, ceilings, floor, and door.
 - If using a household-grade unit, do not store vaccines/diluents directly under cooling vents; in deli, fruit, or vegetable drawers; or on refrigerator door shelves.
 These areas may expose vaccines to unstable temperatures and insufficient air flow.
- Label shelves/containers to identify where each type of vaccine/diluent is stored.
- Store vaccines/diluents with similar packaging/names or with pediatric/adult formulations on different shelves.
- Store diluents with the corresponding refrigerated vaccine. Never store diluent in a freezer. Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units.
 - If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins from vaccine.

- Potentially contaminated items (e.g., blood, urine, stool) should be properly contained and stored below vaccines due to risk of contamination from drips or leaks.
- The freezer of a combination household-grade unit may be used for non-vaccine, medical storage, as long as the use does not compromise the temperature range within the refrigerator compartment where vaccine is stored.
- Arrange vaccines/diluents in rows and allow space between them to promote air circulation.
- Place vaccines/diluents with the earliest expiration dates in front of those with later expiration dates.
- Place water bottles on the top shelf, floor, and in the door racks. Putting water bottles
 helps maintain stable temperatures caused by frequently opening and closing unit doors
 or a power failure.
 - Water bottles are not recommended for use with certain pharmaceuticalgrade and purpose-built units. For such units, follow the manufacturer's quidance.

Regular Maintenance of Equipment

Vaccine storage units and DDLs require regular maintenance to ensure proper operation. On a regular basis, check seals and door hinges, clean coils and other compartments per manufacturer direction, defrost manual-defrost freezers when the frost exceeds either 1cm or the manufacturer's suggested limit (when defrosting, store vaccines temporarily in another unit with appropriate freezer temperatures), clean the interior of each unit to discourage bacterial and fungal growth, and test any back-up generator quarterly and have it served annually.

Section Four: Pfizer COVID-19 Vaccine Storage

Using the Thermal Shipping Container for Vaccine Storage

Vaccine that is stored in a thermal shipping container should maintain temperatures between -80°C and -60°C (-112°F to -76°F). The thermal shipping container should be stored at 15°C to25°C (59°F to77°F). **Thermal shipping containers may not be used for vaccine storage beyond 30 days.** Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

A Digital Data Logger (DDL) capable of monitoring ultra-cold temperatures must be placed in the location of the vial tray if the thermal shipping container is being used for storage. CDC will provide a temporary DDL with each thermal shipper that may be activated while utilizing the container for vaccine storage. All DDLs purchased separately must have a current, valid Certificate of Calibration.

The thermal shipping container should be re-iced every five days. Re-icing every 5 days helps maintain the level of dry ice and the temperature of the vaccine product. The thermal shipping container should not be opened more than 2 times per day and should not be opened for more than three (3) minutes at a time. Strict adherence to this guideline will ensure the thermal shipping container can maintain ultra-cold storage conditions.

To properly replenish the container, add dry ice to the maximum lines within the payload insert areas and dry ice pod. The thermal shipper and Controlant temperature data logger should be returned to Pfizer within 30 business days of delivery.

Vaccine vials should be protected from light and kept in the original packaging. Vials should always remain upright in trays during storage. If a vial is touched, it is considered "thawed" and is to be moved to the refrigerator for use within 5 days. If the lid of the vial tray is opened, it must be returned to ultra-cold storage within three (3) minutes and must stay in ultra-cold storage for two (2) hours before the tray is opened again. When transferring between ultra-cold environments, the 195-vial box may be at room temperature for up to five (5) minutes if the lid is closed and intact.

Vaccine that is stored in the thermal shipping container with the temporary DDL provided will be continuously monitored. Providers using this method of vaccine storage will not be required to document minimum and maximum daily temps, as the DDLs provided will not have a temperature display. Instead, providers utilizing this method of vaccine storage should review and print the DDL reports provided by Pfizer and/or Controlant to each Primary and Back-up Vaccine Coordinator listed on the COVID-19 Provider Agreement.

Using an Ultra-cold Freezer for Vaccine Storage

Vaccine that is stored in an ultra-cold freezer should be stored between -80°C and -60°C (-112°F and -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition. All Pfizer COVID-19 vaccine preparations, so long as they are unopened and untampered with, may be stored in an ultra-cold freezer until the expiration date. Vaccines expire 9 months after the manufacture date.

Vaccine vials should be protected from light and kept in the original packaging. Vials should always remain upright in trays during storage. If a vial is touched, it is considered "thawed" and is to be moved to the refrigerator for use within 5 days. If the lid of the vial tray is opened, it must be returned to ultra-cold storage within three (3) minutes and must stay in ultra-cold storage for two (2) hours before the tray is opened again. When transferring between ultra-cold environments, the 195-vial box may be at room temperature for up to five (5) minutes if the lid is closed and intact.

Vaccine stored in ultra-cold freezers must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Using a Freezer for Vaccine Storage*

Pfizer/BioNTech COVID-19 for 12 years and older (purple cap) vaccine that is stored in a freezer should be stored between-25°C and -15°C (-13°F to 5°F). Pfizer/BioNTech COVID-19 vaccine for 12 years and older (purple cap) may be stored in a freezer for up to two (2) weeks. **NOTE: Vaccine should never be placed into the freezer compartment of a combination refrigerator/freezer unit.** Vaccine stored at frozen temperatures **must** be stored in a separate, approved standalone freezer. Undiluted vials may be stored at room temperature for no more than 2 hours. After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.

*Note that Pfizer Tri-Sucrose COVID-19 vaccine for 12 years and older (gray cap) MAY NOT be stored in the freezer. Pfizer for 5 to 11 years old (orange cap) MAY NOT be stored in the freezer.

Frozen vials stored or transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). This includes vials that are held up to two weeks at -25°C to -15°C (-13°F to 5°F), and at risk of not being used in time. Any time that the vials are stored or transported at -25°C to -15°C count against the two-week limit. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed two weeks. CDC is updating Pfizer Beyond-Use Date Labels to track this two-week timeframe.

Vaccine stored in freezers must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures

for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Using a Refrigerator for Vaccine Storage

Vaccine that is stored in a refrigerator should be stored between 2°C and 8°C (35°F to 46°F). Pfizer/BioNTech COVID-19 vaccine for 12 years and older (purple cap) may be stored in a refrigerator for up to one month. Pfizer Tri-Sucrose COVID-19 vaccine for 12 years and older (gray cap) may be stored in a refrigerator for up to 10 weeks. Pfizer for 5 to 11 years old (orange cap) may be stored in a refrigerator for up to 10 weeks.

Vaccine stored in refrigerators must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Vaccine Storage at Room Temperature

Vaccine that is stored at room temperature should be stored between 8°C and 25°C (46°F to 77°F). Pfizer for Individuals 12 years and older (PURPLE Cap) may be stored at room temperature for no more than 2 hours prior to dilution (including any thaw time). After dilution and/or first puncture, vials may be kept at room temperature for no more than 6 hours.

Pfizer Tri-Sucrose for individuals 12 years and older (GRAY Cap) may be kept at room temperature for no more than 12 hours. Note: this formulation does not require dilution prior to administration.

Pfizer for individuals 5 -11 years old (ORANGE Cap) may be kept at room temperature for 12 hours prior to dilution (including any thaw time). After the first puncture at room temperature discard after 12 hours.

Section Five: Moderna COVID-19 Vaccine Storage

Using a Freezer for Vaccine Storage

Moderna COVID-19 vaccine that is stored in a freezer should be stored between -50°C and - 15°C (-58°F to 5°F). Moderna COVID-19 vaccine may be stored in a freezer for up to six (6) months.

NOTE: Vaccine should never be placed into the freezer compartment of a combination refrigerator/freezer unit. Vaccine stored at frozen temperatures must be stored in a separate, approved standalone freezer. Vaccine stored in freezers must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Using a Refrigerator for Vaccine Storage

Moderna COVID-19 vaccine that is stored in a refrigerator should be stored between 2°C and 8°C (35°F to 46°F). Unpunctured vials may be stored in a refrigerator for up to 30 daysVaccine stored in refrigerators must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Vaccine Storage at Room Temperature

Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 24 hours. After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F) and should be discarded 12 hours after the first puncture. Note: after a vial is punctured 20 times, it should be discarded even if the 12 hour time limit has not been met.

Section Six: Janssen COVID-19 Vaccine

Vaccine Storage

Janssen COVID-19 vaccine that is stored in a refrigerator should be stored between 2°C and 8°C (35°F to 46°F). **Do not store Janssen COVID-19 vaccine in a freezer or ultra-cold freezer.**

Janssen COVID-19 vaccine may be stored in a refrigerator for up to three (3) months Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.

The Janssen COVID-19 Vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 2 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed. After the first dose has been withdrawn, the vial may be stored in the refrigerator between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours.

Vaccine stored in refrigerators must be continuously monitored by a DDL with a current, valid Certificate of Calibration. It is required that temperatures are reviewed for each vaccine storage unit twice each day (morning and afternoon) and that the minimum and maximum temperatures for the past 24 hours are reviewed each morning. These temperature readings must be documented daily, as should actions that are taken if the temperature readings are out of acceptable range.

DDL reports must be printed, reviewed, and signed by the Primary or Back-up Vaccine Coordinators each week and maintained with temperature logs for three years.

Section Seven: Temperature Excursions (TEs)

Temperature excursions (TEs) occur when there is a temperature reading outside of the recommended temperature range for a vaccine. When a TE occurs, the vaccine manufacturers.

- Pfizer: 1-800-TRY-FIRST (1-800-879-3477) Monday Friday 9:00 AM to 7:00 PM EST
 - Controlant: USA: (855) 44-CONTROL Support: support@controlant.com
- Moderna: 1-866-MODERNA (1-866-663-3762) 24 hours, 7 days a week
- Johnson & Johnson: (800) 526-7736, Monday Friday 9:00 AM to 8:00 PM EST

Notify vaccine manufacturers if one of the following occurs Refrigerated vaccines reach temperatures colder than 2°C or warmer than 8°C

Frozen vaccines reach temperatures colder than -25° or warmer than -15°C

Ultra-cold vaccines reach temperatures colder than -95°C or warmer than -60°C

TE is part of a pattern of frequent excursions, regardless of duration

TE concerns regardless of one of the above criteria

If a TE occurs, follow these steps:

- Troubleshoot to see if you can identify why unit went out-of-range (e.g., unit is unplugged, unit door is open or not sealed adequately, thermostat is set incorrectly, probe has been moved from center of unit, or coils and vents have excess dust) and attempt to return vaccine to proper storage conditions if still out-of-range by.
 - a. If outside of business hours and temperature is still out-of-range and cannot be restored to proper temperatures, execute an emergency plan.
- 2. Label vaccines "Do not use" and do not use until manufacturers are contacted.
- 3. Call vaccine manufacturer(s) for further instruction.
- 4. Download DDL report, noting how long the temperature has been out of range and the minimum/maximum temperatures.
- 5. Provide the DDL report/temperature log information to the vaccine manufacturer.
- 6. Wait for notification from the manufacturer whether the vaccine can be used.

Section Eight: Vaccine Inventory Management

The vaccine cold chain becomes the provider's responsibility once delivery is made to the facility. The following section provides information on ensuring that vaccines are unpacked, stored, prepared, administered, and transported correctly.

Scheduling and Receiving Deliveries

Staff members who may accept deliveries should be trained to immediately notify the vaccine coordinator or other designated personnel when deliveries arrive.

Unpacking Deliveries

Upon arrival, follow the manufacturer's guidance for unpacking the vaccine. Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately after arrival. Check the shipment to ensure:

- No damage occurred to the package during transport
- The correct types and quantities of vaccines (and diluents, if applicable)

- No expired or soon-to-expire products were shipped
- No TEs occurred during transit (using the cold chain monitor [CCM])

Unopened/unpacked boxes should not be placed in a storage unit because the cool packs shipped with the vaccine can make the vaccine too cold if placed inside the storage unit.

Ultra-cold vaccine may be shipped in coolers packed in dry ice. These coolers should be repacked with dry ice within 24 hours of receipt and repacked again within 5 days or per manufacturer recommendations.

Stock Rotation and Removal

On a regular basis, vaccine stock should be rotated and checked for expired doses. Expired vaccines and diluents should be removed immediately to avoid inadvertent administration. Vaccines with earlier expiration dates should be placed in front of those with later expiration dates.

Preparing Vaccines for Administration

Preparing vaccines is the final step in the cold chain before administering to the patient. Best practices for handling vaccines include:

- Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
- Only prepare vaccines when you are ready to administer them.
- Check expiration dates and confirm that you have selected the correct vaccine.
- Only administer vaccines you have prepared.

Section Nine: Vaccine Transport

Emergency Vaccine Transport

Vaccines should not be routinely transported. However, emergencies such as storage unit failure or power outage may require vaccine transport; in these instances, ensure precautions are taken to protect your supply by using the appropriate packing materials and procedures. CDC's Packing Vaccines for Transport during Emergencies is a useful tool that details proper procedures for doing so. Highlights include:

- Diluents should be included with their corresponding vaccines during transport to ensure there is always an adequate amount for reconstitution.
 - If diluents typically stored at room temperature (20°C to 25°C [68°F to 77°F])
 will be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible so they do not raise the container temperature

when placed with refrigerated vaccines. Diluents should **never** be frozen, even during transport. When packing vaccines and diluents for transport, place an insulating barrier like bubble wrap between the diluents and conditioned water bottles or phase change materials.

- Maintain a sufficient supply of materials needed for emergency vaccine transport of your maximum inventory. Materials include:
 - Portable vaccine refrigerators/freezer units (preferred)
 - Qualified containers and packouts
 - o Hard-sided insulated containers or Styrofoam™
 - Coolant materials such as phase change materials (PCMs) or frozen water bottles that can be conditioned to 4°C to 5°C
 - Follow manufacturer's instructions for use to reduce the risk of freezing vaccines during transport
 - Insulation materials such as bubble wrap and corrugated cardboard enough to form two layers per container
 - DDLs for each container

Soft-sided containers specifically engineered for vaccine transport are acceptable. Do not use commercially available soft-sided food or beverage coolers because most are poorly insulated and likely to be affected by room or outdoor temperatures. In an emergency situation, a system with conditioned water bottles can be used.

Never use commercially available soft-sided food or beverage coolers, and only use the original shipping materials that vaccines were initially shipping on or conditioned water bottle transport systems as a last resort in emergencies. In **no situation** should the frozen gel packs or coolant packs from the original shipments be re-used.

Planning and Preparing for Transport

Emergency vaccine packing and transport protocols should be included within your facility's SOPs to ensure you are prepared for a situation in which your vaccine supply must be transported.

- Staff should be trained to pack vaccines correctly.
- Prior to transport, take an inventory of vaccines and record actions to protect vaccines during transport.
- Use the COVID-19 vaccine Transport log in Appendix B to record the time vaccines
 are removed from the storage unit and placed in the transport container, the
 temperature during transport, and the time at the end of transport when vaccines are
 placed in a stable storage unit.
- When in transport, only open unit doors when necessary and only after all preparation for packing and moving vaccines has been completed.
- Avoid leaving containers where they may be exposed to direct sunlight.
- Check vaccine temperature upon arrival at the alternative vaccine storage facility and store vaccines at recommended temperatures immediately.

Monitoring Temperatures During and After Transport

While in transport, vaccines should still be continuously monitored using a DDL. DDLs used in vaccine transport have the same requirements as the ones used during routine storage and handling. Upon arrival at the destination, vaccines should be immediately stored in a storage unit with a DDL. A DDL report from the DDL used in transport should be printed, reviewed for TEs, and maintained with COVID-19 vaccine records for three (3) years.

Section Ten: Emergency Vaccine Storage and Handling

Equipment failures, power outages, severe weather conditions, and natural disasters can happen without warning and may compromise vaccine storage conditions. In addition to vaccine transport planning, additional plans should be in place for emergencies.

You may choose to have a backup storage unit within your facility where vaccine can be stored if the primary storage unit fails. Additionally, you may have a generator that is activated if power is compromised to the facility. However, even if a generator is available, additional backup plans should be in place for transport out of the facility.

Alternative Storage Facility

A working agreement should be established with at least one alternative storage facility as part of emergency vaccine storage and handling planning. This agreement should include 24-hour access to this facility.

After Hours Facility Access

A relationship with your facility's building manager and/or security staff should be maintained to ensure that you are able to access your vaccine supply outside of normal business hours. Relevant staff should maintain copies of information regarding building access and security procedures at home.

Appendix A

Routine and Emergency Vaccine Management Plan (REVMP)

KEEP YOUR MANAGEMENT PLAN NEAR VACCINE STORAGE UNITS

The Virginia Department of Health, Division of Immunization requires COVID-19 Vaccination Program providers to maintain a vaccine management plan for routine and emergency situations. This document is a template for information, such as guidelines, protocols, contact information, and staff training, about your practice. None of the information included in this template may be excluded in the plan.

Review and update your plan at least once a year, when COVID-19 Vaccination Program requirements change, and when staff with designated vaccine management responsibilities change. Key practice staff must sign and acknowledge the signature log annually and whenever your plan is revised.

CDC Site Visit Reviewers may ask to review your plans during routine and drop-in site visits.

STAFF ROLES AND CONTACT INFORMATION			
Facility Name:			
Facility Phone Nu	ımber:	COVII	D PIN:
Role/Responsibility	Name	Phone Number	Email Address
Chief Medical Officer			
Chief Executive Officer or Chief Fiduciary Officer			
Primary Vaccine Coordinator			
Back-up Vaccine Coordinator			
Pharmacist			
Receives Vaccines			
Stores Shipping			
Handles Vaccines			

Please refer to <u>Page 3</u> of this document for descriptions of the key duties assigned to designated vaccine management staff. Staff must sign and date the <u>Acknowledgement and Signature Log</u> at the end of this document to confirm that they understand and agree to the duties assigned to them.

COVID-19 REQUIRED TRAINING LOG

Please list designated vaccine management personnel and have them sign and acknowledge that they have completed required training.

Primary and Back-up Vaccine Coordinators must complete CDC's COVID-19 Vaccine Training Modules. Additionally, if a pharmacist is listed as the signatory under the Storage and Handling section of the COVID-19 Provider Agreement, this individual must complete the training modules. These modules include a <u>General Overview of Immunization Best Practices</u>, <u>Moderna COVID-19 Vaccine</u>, <u>Janssen COVID-19 Vaccine</u>, and <u>Pfizer COVID-19 Vaccine</u>. Staff at your facility that routinely handle or administer COVID-19 vaccines are recommended to also participate in these trainings, in case of staff turnover.

		Date Training Completed			
Name and Title	Signature	General Overview	Moderna	Pfizer	Janssen
Primary Vaccine Coordinator					
Back-up Vaccine Coordinator					
Pharmacist					
Filailiacist					

KEY DUTIES FOR DESIGNATED VACCINE MANAGEMENT STAFF

All staff who work with COVID-19 vaccines should be familiar with all requirements outlined in the COVID-19 Vaccination Program Provider Agreement. Below are highlights of key duties for designated vaccine management staff.

CMO/CEO:
Complies with all federal vaccine management requirements, including key areas outlined in this plan
Oversees designated vaccine management staff to ensure COVID-19 program requirements are being met
Designates one employee as Primary Vaccine Coordinator
Designates one employee as Back-up Vaccine Coordinator
Authorizes and reports changes to Primary and Back-up Vaccine Coordinators, CEO, or CMO to the COVID-19
onboarding team as soon as possible following any changes
Meets and documents required training for designated vaccine management staff
Ensures designated vaccine management staff are skilled and knowledgeable regarding temperature monitoring and
storage equipment requirements
Ensures practice's vaccine inventory management is consistent with program requirements Ensures practice's
vaccine storage units and temperature monitoring devices meet program requirements
Updates and revises vaccine management plans at least annually and whenever necessary
Reviews program requirements and management plans with staff at least annually and whenever necessary
Primary Vaccine Coordinator:
Completes all required training modules
Maintains COVID-19 vaccine in accordance with all CDC requirements outlined in the Provider Agreement
Back-up Vaccine Coordinator:
Completes all required training modules
Maintains COVID-19 vaccine in accordance with all CDC requirements outlined in the Provider Agreement
Pharmacist (only required if a pharmacist signed Storage and Handling section of Provider Agreement):
Completes all required training modules
Maintains COVID-19 vaccine in accordance with all CDC requirements outlined in the Provider Agreement

The Primary Vaccine Coordinator should review and acknowledge the following requirements by checking the box next to each item:

VACCINE STORAGE EQUIPMENT

Equipment:
This facility uses compliant vaccine storage refrigerator(s) and/or freezer(s) Vaccine storage units
Maintains recommended unit temperature ranges:
Refrigerator: between 2 and 8 °C
• Freezer: between -15 °C and -25 °C
 Ultra-cold Freezer: between -96 °C and -60 °C
☐ Vaccine storage units have adequate capacity to store vaccine supply at all times
Vaccine storage units are routinely cleaned inside, kept dust-free outside, and have proper seals on the doors This
facility keeps maintenance and repair records for vaccine storage units
Power Supply:
Each vaccine storage unit is directly plugged into a wall outlet
No vaccine storage unit is controlled by a light switch, power strips, or surge protectors with on/off switch
Extension cords are never used to connect storage units to an outlet
Plug guards are used to prevent power interruption
"DO NOT UNPLUG" signs are posted at each outlet and at the circuit breakers
Set-up:
Vaccine storage units are set up according to requirements outlined in the CDC Storage and Handling Toolkit
Vaccine storage units are located away from direct sunlight and away from walls to allow air circulation Vaccines are
never stored in the doors, drawers, or bins of storage units
Drawers/deli crispers are removed from vaccine storage units
Vaccines are stored 2-3 inches away from the walls, air vents, and floors of vaccine storage units to allow space for
air circulation
To stabilize temperatures, frozen cold packs are kept in standalone freezers and water bottles are kept on the top
shelf, in the door, and on the bottom of refrigerators where vaccines cannot be stored.
The freezer compartment of a combination refrigerator/freezer storage unit is NEVER used for vaccine storage
Dorm-style units are NEVER used for vaccine storage
Vaccines are organized in plastic mesh baskets and clearly labeled by type of vaccine Buffered
DDL probes are placed in the center of the vaccine storage units, near the vaccines DDL displays
are securely attached on the outside of vaccine storage units
Vaccines are stored in their original packaging until administered
Food, beverages, and laboratory specimens are never stored in vaccine storage units
When medication or biologic media (not inoculated) are stored in the same unit as vaccines, they are placed on the
shelves below vaccines

TEMPERATURE MONITORING EQUIPMENT

Digital Data Loggers (DDLs):
Each vaccine storage unit has a continuous temperature monitoring device with the following capabilities:
Data that can be routinely downloaded
Active display that is placed on the outside of the unit door to allow for reading temperatures without opening the unit door
Detachable, buffered probe to help approximate the vaccine temperature rather than the air temperature Alarm for out-of-range temperatures
Low battery indicator
Accuracy of +/- 0.5°C
Memory storage of at least 4,000 readings
User-programmable logging interval (or reading rate)
Each DDL has a current and valid Certificate of Calibration (also known as a Report of Calibration Testing)
Each DDL has a digital display of current, minimum, and maximum temperatures
Each DDL displays temperatures in degrees Celsius (°C) Each
Each DDL is set to alarm when:
 Temperature in refrigerator goes above 8°C or below 2°C
Temperature in freezer goes above -15°C or below -25 °C
Probes are placed in the center of vaccine storage units and never in the unit doors, near or against the walls,
underneath air vents, or on unit floors
DDL batteries are replaced every six months or as needed
There is at least one back-up DDL that is readily available on-site to ensure that temperature assessment and recordings
can be performed twice a day
DDL Calibration:
All primary and back-up DDLs are calibrated as recommended by the manufacturer
DDL calibration is done by either a laboratory accredited by an ILAC MRA signatory body or an entity that provides
documentation demonstrating that calibration testing meets ISO/IEC 17025 International standards for calibration testing and traceability
Certificates of Calibration are maintained in a readily accessible area, until expiration
DDLs are replaced on or before expiration date listed on device
DDLs are replaced when no longer accurate within +/- 0.5°C
Safeguarding Vaccines, Handling, and Reporting Temperature Excursions:
When an out-of-range temperature is identified, immediate action is taken to assess the situation and to prevent vaccine spoilage
Temperature excursions are reported immediately to the vaccine manufacturer(s)
Vaccines involved in temperature excursions are labelled "Do Not Use"
This facility has an Emergency Vaccine Management Plan to follow in case of power outage, appliance
malfunction, severe weather conditions, or human error that may affect vaccine viability
When necessary to transport vaccine to another storage unit or to a predetermined site, facility always follows CDC's
Packing Vaccines for Transport during Emergencies Job Aid

Temperature Monitoring and Documentation:
Vaccine storage unit temperatures are read twice a day, when the clinic opens and before it closes
Minimum and maximum temperatures are read and recorded once each day
AM temperatures are read and recorded before opening vaccine storage units
PM temperatures are read and recorded at the end of each day, allowing time for corrective actions in the event of
out-of-range unit temperatures
INVENTORY MANAGEMENT
Inventory Maintenance:
Physical vaccine inventory is reconciled in VIIS daily
Facility has adopted an inventory control system
Accurate records, including packing slips and inventory management records
☐ Vaccines that are drawn up and not used are disposed of correctly and recorded in VIIS
Facility stores diluent for vaccine appropriately
Facility clearly labels diluents that are not packed with its vaccine so they can be easily identified
Diluents are not placed in the freezer
Stock Rotation, Returns, and Transfers
Vaccine stock is rotated monthly to assure that vaccines with the shortest expiration dates are used first
If vaccine expires or spoils, it is:
Removed from storage unit
Reconciled appropriately in VIIS
If vaccine is due to expire within two weeks and will not be used, this facility will:
 Transfer (if possible) the vaccine to prevent waste to another enrolled provider
Document the transfer in <u>VaxMaX</u>
If facility needs to transfer or transport vaccine, CDC's Packing Vaccines for Transport during Emergencies Job Aid
is followed
This facility does not return the following items:
Used syringes with or without needles
Syringes with vaccine drawn up and not used
Broken or damaged vaccine vials Multiplicate a viale that have already be an with decrease.
Multi-dose vials that have already been withdrawn Spelled expired or wested vession are reported to VDH before pleating a new vession order.
Spoiled, expired, or wasted vaccine are reported to VDH before placing a new vaccine order
 All vaccine COVID-19 vaccine waste must be reported to VDH by completing the <u>COVID-19 Wastage Form</u>
Vaccine Ordering:
NOTE: While supplies are limited, VDH will continue to allocate doses and approve doses sent directly
to providers.
Orders are submitted in VIIS and placed according to clinic-based eligibility data, assigned order frequency, vaccine
usage, and current inventory in stock.
A physical vaccine inventory is conducted before placing a vaccine order
This facility places orders with sufficient inventory on hand to allow time for order processing delivery
This facility confirms operation hours in VIIS before submitting each order

This facility reports any changes to the practice's hours to VDH to avoid receiving vaccine shipments when the clinic is closed or staff is not available
Receiving and Inspecting Vaccine Shipments:
Staff is familiar with procedures for accepting vaccine shipments in VIIS
Vaccine shipments are inspected immediately upon arrival to verify that the temperature during transport was within
range, and that the vaccines being delivered match those listed on the packing slip and order confirmation
This facility assumes responsibility for all COVID-19 vaccine that is shipped to its site
This facility never rejects a vaccine shipment
Shipment discrepancies and vaccines exposed to out-of-range temperatures are reported to
the vaccine manufacturers immediately
☐ Vaccines are stored immediately and appropriately upon delivery
Vaccines are accepted in VIIS inventory upon receipt

VACCINE STORAGE UNIT INFORMATION

Unit Type	Unit Location	Brand	Model Number	Serial Number
Refrigerator (1)				
Refrigerator (2)				
Refrigerator (3)				
Refrigerator (4)				
Freezer (1)				
Freezer (2)				
Freezer (3)				
Freezer (4)				
Where are your digital data logger reports and temperature logs located?				
If you have a	manual defrost freezer,	please provide a descripti	on of your plan for regul	ar defrosting *:
* A dofroct!-	up to required for provide	ers with a manual defrost fr	pozor. The plan should	inglude 1) where you will

VDH must be notified before transporting vaccines, and all temperature excursions that occur during transport must be reported.

^{*} A defrost plan is required for providers with a manual defrost freezer. The plan should include 1) where you will transfer vaccines, 2) what equipment will be used to transfer vaccines, and 3) when/how often you will defrost your freezer.

DIGITAL DATA LOGGER AND CALIBRATION INFORMATION

Primary Data Loggers (must have one for each unit listed in previous section):					
DDL Brand, Model # /Serial #	Calibration Date	Calibration Expiration Date	Low Alarm Setting	High Alarm Setting	
Primary Data Loggers (1	must have at least one read	lily available on-site):			
Data Logger Model/Serial #	Calibration Date	Calibration Expiration Date	Low Alarm Setting	High Alarm Setting	
Calibration Compa	Calibration Company:Phone Number:				
Location of Certificates of Calibration:					

USEFUL EMERGENCY NUMBERS

Service	Name	Main Phone Number	Alternate Number	Email Address
Utility Company				
Building Maintenance				
Building Alarm Company				
Refrigerator/Freezer Alarm Company				
Refrigerator/Freezer Repair Company				
Point of Contact for Vaccine Transport				

VDH Team	Main Phone Number	Email Address
Temperature Excursions (available Monday – Friday, 8AM – 4:30PM)	(877) 829-4682	covidvaccineinfo@vdh.virginia.gov
Vaccine Storage and Handling	(877) 829-4682	covidvaccineinfo@vdh.virginia.gov
VIIS Help Desk (available Monday Friday, 7AM – 6PM)	(866) 375 – 9795	VIIS_Helpdesk@vdh.virginia.gov

Emergency Vaccine Management Plan

The following sections include space for information and necessary actions to take in the event of an emergency, such as unit malfunction, mechanical failure, power outage, natural disaster, or human error.

In an emergency, contact the following people in the order listed:

Role/Responsibility	Name	Phone Number	Email Address	
	l			
Does the clinic have a	generator? If so, where is it loo	cated?		
If your clinic does not h	nave a generator, and/or your v	vaccine storage unit fails, it may	be necessary to transport	
	orage locations.* Please identif	=	,	
Alternate Vaccine Storag	e Address and City	Point of Contact Name	POC Contact Information	
Location	,			
* Alternate storage lo	cations must have vaccine s	torage units and continuous	temperature monitoring equipment	
_		by the CDC Storage and Hand	• • •	
I have confirmed th	at the point of contact for the a	alternate storage locations will a	accept my vaccines during an emergenc	
situation.				
Signature:Date:				
Where is the location of	of your emergency packing sup	pplies?		
		•		

If you have a generator and no back-up locations, the generator should be tested quarterly and serviced once a year. In the section below, please record the last date that the generator was tested and serviced and sign and date each time this occurs during the year.

The REVMP does not need to be re-submitted each time the generator is tested or serviced, but it will be reviewed during routine and drop-in site visits:

Quarterly Tests

Quarter	Signature	Date
Q1		
Q2		
Q3		
Q4		

Annual Service	
Signature:	Date:

OTHER USEFUL EMERGENCY INFORMATION

Complete the following information for emergency storage units that will be used by your facility for emergencies that do not require an alternate storage location.*

Unit Type	Unit Location	Brand	Model Number	Serial Number
Refrigerator (1)				
Refrigerator (2)				
Freezer (1)				
Freezer (2)				
* Alternate stora	ge locations must have v	accine storage units and	d continuous temperatui	e monitoring equipment
that is in compli	ance with requirements of	outlined by the CDC Stor	age and Handling Toolk	<u>it</u>
Use the followin	g guidance for safeguard	ling vaccines in the ever	nt of planned or unplanne	ed power
interruptions (e.	g. power outages, severe	weather, building maint	tenance/repairs, etc.):	
Before an Emerg	gency:			
Maintain eme	rgency contact information	for designated vaccine ma	anagement personnel	
Place water b	ottles on the top shelf, in th	e door, and on the bottom	of vaccine refrigerators, w	here vaccines cannot
be stored and	in freezers to stabilize tem	nperatures.		
Identify altern	ate vaccine storage locat	ions (e.g. a local hospital	l, a local health departme	ent, or another COVID-19
provider). Ens	sure the location has adec	quate space to accommod	late vaccines and that the	eir temperature monitoring
equipment me	eets requirements.			
Update neces	ssary contact information	for alternate vaccine sto	rage locations, including	facility name, address,
contact perso	n, and telephone number.			
Stock emerge	ency supplies as indicated	in CDC's Packing Vaccine	es for Transport during En	nergencies Job Aid Label
	essible any necessary vac oor plans when available, a	, ,		ne transport job
Be familiar wi	Be familiar with back-up power sources for commercial, laboratory, and pharmacy-grade storage units			
During an Emerg	gency:			
Assess the sit	tuation. Do not open the va	ccine storage unit.		
Determine the	e cause of the power failure	e and estimate the time it v	vill take to restore power.	
Notify key vac	cine management staff list	ed on the Emergency Plan	n as appropriate	
If the power o	utage is expected to be sh	ort-term, usually restored	within 2 hours:	
Record th	_	ted, unit temperatures (cu	rrent, minimum, and maxir	num) for each day, and the
Place a "[OO NOT OPEN" sign on the	e storage unit(s) to conser	ve cold air mass	
Monitor th	ne temperature until power	is restored		
If the outage i	s expected to be long-term	n, usually longer than 4 ho	urs, consider moving	
vaccines to a	n alternative unit or facility.	See details below, under	Relocating Vaccine.	

NOTE: Temperatures in vaccine storage units tend to increase faster during power outages. As a result, clinics may need to monitor temperature more frequently and/or transport vaccines to an alternate location sooner.

Relocating Vaccine:

If a power outage is expected to be long-term (e.g. not restored by the end of the day) or storage units are not working properly, prepare to relocate vaccines to alternate storage locations. If moving vaccines, <u>a DDL must remain with the vaccine at all times</u>.

Before transporting vaccines:
Review CDC's Packing Vaccines for Transport during Emergencies Job Aid
Contact the alternate storage facility to verify that they can accept the vaccines
If transport or relocation is not feasible (e.g. alternate location is not available or travel conditions are unsafe):
Keep units closed and document the current, minimum, and maximum temperatures for each day
Packaging and transporting vaccines:
Complete the Refrigerated/Frozen Transport Log (Appendix B)
Attach DDL to cooler
Prepare cooler(s) for transport following CDC's Packing Vaccines for Transport during Emergencies Job Aid
Use frozen cold packs for frozen vaccines. Never use dry ice.
Use conditioned (slightly defrosted) frozen packs for refrigerated vaccines. Placing refrigerated vaccine directly on frozen packs and packaging it without sufficient insulation may freeze and therefore, damage vaccine. If clinic
does not have time to condition frozen packs, refrigerated cold packs or cold water bottles may be used.
Package and prepare diluent
Diluents stored in the refrigerator should be transported with refrigerated vaccines
Diluents stored at room temperature should be transported at room temperature
Diluents packaged with their vaccine should be transported with their vaccine
Upon arrival at the alternate vaccine storage location, document total vaccine transport time, the current,
minimum, and maximum temperatures in the transport cooler(s), and the current, minimum, and maximum temperatures in the alternate storage unit(s).
After Power is Restored:
Verify storage units are functioning properly and temperatures are within range before attempting to move any vaccin
Follow the same transportation procedures and transfer vaccine back to its original storage unit
Vaccine kept at the proper temperature during the power outage, whether transported or not, may be used
For any vaccine not stored at proper temperature:
Segregate it in the storage unit
Mark it "Do Not Use"
Contact the vaccine manufacturer(s) to report the excursion
 Pfizer: 1-800-TRY-FIRST (1-800-879-3477) Monday through Friday 9:00 a.m. to 7:00 p.m. EST
 Controlant: USA: (855) 44-CONTROL Support: support@controlant.com
 Moderna: 1-866-MODERNA (1-866-663-3762) 24 hours, 7 days a week
 Johnson & Johnson: (800) 526-7736, Monday – Friday 9:00 AM to 8:00 PM ET.
All vaccine COVID-19 vaccine waste must be reported to VDH by completing the COVID-19 Wastage Form

Acknowledgement and Signature Log

Please sign and date this acknowledgement and signature log when you update practice-specific information.

By signing this log, facility staff are acknowledging that they have reviewed, understand, and agree to the key duties assigned to them as vaccine management personnel for this facility.

Updates and comments to changes made in Routi	ne and Emergency Vaccine Management Plans:	
CMO:		
Name:		
Signature:	Date:	-
	_	
PRIMARY Vaccine COORDINATOR:		
Name:		
Signature:		<u>-</u>
	_	
BACK-UP Vaccine COORDINATOR:		
Name:		
Signature:		<u> </u>
	_	
CEO/CFO:		
Name:		
Signature:		
	<u> </u>	
Pharmacist (if applicable):		
Nama		
Name:		
Signature:	Date:	
Name:		
Signature:	Date:	

Appendix B

COVID-19 Vaccine Refrigerated/Frozen Vaccine Transport Log Date: _

Instructions: Complete this log when transporting vaccines to an alternate or back-up refrigerator/freezer.

Provider Name:				COVID/VFC PIN:			
Transferred To:COVID/VFC PIN:							
Vaccines T	ransferred Due To:	□ Power Outage □ Excess	s Supply	□ Unit Malfunction □	Building Maintenance □	Other:	
Date Transı	ported:						
Vaccine	Inventory Info	ormation – may als	so attach most re	ecent reconciliat	ion report from \	/IIS.	
Vaccine	Lot Number	Number of Doses	Expiration Date	Vaccine Previousl (Yes/No)	y Transported?	Comments	
Tempera	ature Monitori	ng Information					
Temperature	e of vaccine in refrig	erator/freezer prior to transf	er:Ce	elsius/Fahrenheit:	Time:		
Temperature of vaccine in cooler before departure:			Ce	elsius/Fahrenheit:	Time:		
Temperature of vaccine in cooler upon arrival:		Ce	elsius/Fahrenheit:	Time:			
Temperature of back-up refrigerator/freezer:			Ce	elsius/Fahrenheit:	Time:		
					Total Transport Time:	Min/Hr	