IOWA Health and Human Services
Public Health

Iowa Vaccines for Children (VFC) Program
Vaccine Storage and Handling Plan

Keep this plan posted near vaccine storage units

Facility Name:
Effective Date:
Annual Review Date:

Reviewed By *(VFC nurse Clinician)*:
VFC PIN:

The vaccine storage and handling plan is a guide for safeguarding vaccines and responding to temperature excursion events. Providers should consult CDC's Vaccine Storage and Handling Toolkit for the most current guidance and best practices regarding vaccine storage and handling. Additional details and VFC requirements are outlined in the Iowa VFC Operations Guide.

Digital Data Logger (DDL) Calibration Details			
DDL Identification Number	**Calibration Date**	**Calibration Due Date**	**R—Refrigerator F—Freezer U—Ultra-cold B—Backup**

Routine Vaccine Storage and Handling Guidelines

STORAGE REQUIREMENTS (select all that apply)

- ☐ Vaccine storage units maintain recommended unit temperature ranges. The recommended temperatures are posted on the units:
  - ☐ Refrigerator: 36.0°F (2.0°C) to 46.0°F (8.0°C)
  - ☐ Freezer: -58.0°F (-50.0°C) to +5.0°F (-15.0°C)
  - ☐ Ultra Cold (ULT): -130.0°F (-90.0°C) to -76.0°F (-60.0°C) for Pfizer COVID-19 Ultra Cold storage if applicable
- ☐ Vaccines and diluents are stored according to manufacturer recommendations
- ☐ MMRII (Merck) can be stored in the freezer. This may prevent inadvertent storage of MMRV in the refrigerator and may also prevent MMRII (Merck) vaccine loss in a temperature excursion
  - DO NOT store diluent in the freezer
  - DO NOT store Priorix (GSK) in the freezer. It is an MMR vaccine that can only be stored between 36.0°F and 46.0°F (2.0°C and 8.0°C)

- [ ] Digital data loggers (DDL) with continuous temperature monitoring, recording capability and a current valid Certificate of Calibration Testing is placed in the refrigerator and freezer units. The DDL is equipped with:
  - [ ] A temperature probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand or Teflon)
  - [ ] An active temperature display outside the unit(s) which can be easily read without opening the storage unit door
  - [ ] Current, minimum and maximum temperature display
  - [ ] Logging interval (reading rate) programmed to measure and record temperatures at least twice per hour (every 30 minutes or more frequently)
  - [ ] Alarm for out-of-range temperatures
    - [ ] Refrigerator set to alarm when temperatures are equal to or above 46.1°F (8.1°C) or equal to or below 35.9°F (1.9°C)
    - [ ] Freezer set to alarm when temperatures equal to or above 5.1°F (-14.9°C) or equal to or below -58.1°F (-50.1°C)
    - [ ] Ultra Cold (ULT) set to alarm when temperatures are equal to or above -75.9°F (-60.0°C) or equal to or below -130.1°F (-90.0°C) for Pfizer COVID-19 Ultra Cold storage (if applicable)
  - [ ] Low battery indicator
  - [ ] Recommended uncertainty of +/-0.5 °C (+/-1°F)
- [ ] Each DDL has a current Certificate of Calibration Testing. Recalibration should be completed every 2-3 years or according to manufacturer recommendations. Each certificate must include:
  - Model/Device name and/or number
  - Serial number
  - Date of calibration (report or issue date)
  - Confirmation that the instrument passed testing (or instrument in tolerance)
  - Recommended uncertainty of +/-0.5 °C (+/-1°F)
- [ ] The Certificate of Calibration is issued by an appropriate entity as indicated by one or more of the following:
  - 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) Mutual Recognition Arrangement (MRA) signatory body
  - Traceable to the 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
- [ ] A backup digital data logger is readily available. The backup DDL meets all the above requirements and has a different calibration date than the primary DDL

- [ ] To stabilize temperatures, water bottles are kept on the top shelf, floor and in door racks. Note: water bottles may not be recommended for use with certain pharmaceutical-grade or purpose-built units. For these units, follow manufacturer guidance
- [ ] Vaccine is stored in the center of unit(s) in the original manufacturer packaging with lids closed
- [ ] Vaccine is not stored under cooling vents, in the door of the unit, crisper or in the bottom of the unit(s)
- [ ] No food or beverages are stored the vaccine unit(s)
- [ ] When medication or other biologic products must be stored in the same unit as vaccines, they are clearly marked and stored in separate containers or bins from vaccines
- [ ] When potentially contaminated items (blood, stool, urine specimens) must be stored in the same unit as vaccines, they are properly contained and stored below all vaccines

EQUIPMENT and SAFEGUARDS (Select all that apply)

- [ ] Vaccines are stored according to manufacturer recommendations in one of the following:
  - Purpose-built or pharmaceutical grade unit
  - Household-grade stand alone or combination unit.
    Note: if a combination household refrigerator/freezer unit is used, only the refrigerator section is utilized for storing vaccines. A separate stand-alone freezer is used for frozen vaccines.
- [ ] Dorm/bar-style refrigerator/freezer combination units are never used to store vaccines
- [ ] Warning signs (e.g. Do Not Unplug) are posted on vaccine storage units and at the outlets
- [ ] Circuit breakers supporting vaccine units are clearly marked
- [ ] Safety lock plugs or outlet covers are used to prevent the unit from being unplugged
- [ ] Vaccine storage units are not plugged into a GFI outlet, extension cord or power strip
- [ ] Each vaccine storage unit is directly plugged into a wall outlet; one unit per electrical outlet
- [ ] Vaccine storage unit doors close securely and are free from defects
- [ ] Vaccine storage units are large enough to store vaccine without overcrowding. Consideration should be given to space needed during respiratory season for additional vaccines
- [ ] Routine maintenance is completed for all units. This includes, but is not limited to checking door seals, cleaning coils or other components per manufacturer directions, defrosting manual-defrost freezers, cleaning unit interiors, testing backup generators, or any other routine maintenance.

TEMPERATURE MONTIORING (Select all that apply)

- [ ] DDL(s) are present in each storage unit for temperature monitoring as outlined in the ‘Storage Requirements’ section
- [ ] Minimum and maximum temperature of unit(s) are checked and recorded on a temperature log at the start of each workday along with staff initials and time of reading

- [ ] Real-time temperature checks are performed and recorded twice daily (at the start and end of the workday) along with staff initials
- [ ] Temperature logs are maintained for at least three years for each unit. This may be in electronic or paper format.
  Note: If a digital data logger has the capability to annotate an electronic temperature check with the time and initials of the person performing the check, it is not necessary to manually log the temperature check each time
  - [ ] Designated staff review temperature logs at least once per week to ensure proper temperature recording and act if out-of-range temperatures are found on the logs during review
  - [ ] Data Logger(s) are downloaded and reviewed at least every two weeks and whenever the data logger alarms. Data must be maintained for at least three years in electronic or paper format.
  - [ ] Clinic staff is trained to take immediate action if temperatures are out-of-range. If temperatures are outside of the recommended range, immediate action is taken as outlined in the “Temperature Excursion’ section

VFC VACCINE ORDERING (Select all that apply)

- [ ] Before placing VFC vaccine orders, current inventory and expiration dates are reviewed. Seasonal events and specialty clinics are considered
- [ ] Clinic staff is trained regarding the VFC vaccine ordering process and submit orders through Iowa’s Immunization Registry Information System (IRIS)
- [ ] VFC orders are placed based on the facility’s assigned ordering frequency.
- [ ] Recommended order quantities and current inventory are reviewed and considered before placing a VFC order. Consideration is given to both single antigen and combination presentations
- [ ] Clinic staff do not over-order or stockpile vaccine while maintaining adequate inventory to prevent missed opportunities to vaccinate
- [ ] An adequate inventory of VFC and private (if applicable) vaccine is maintained to eliminate occurrences of borrowing between VFC and private inventories

RECEIVING VACCINE (Select all that apply)

- [ ] A protocol is posted for all staff on accepting vaccine deliveries and whom to contact regarding vaccine shipments
- [ ] The facility is available to receive VFC vaccine shipments at least one day per week on a day other than Monday for at least four consecutive hours during the day.
- [ ] Clinic staff checks the cold chain monitor included in the shipment to ensure the vaccine was maintained at appropriate temperatures while shipping.
- [ ] When reviewing packing slips for frozen vaccines, staff check and verify the maximum amount of time vaccines can be in transit, and ensure the time has not been exceeded

- [ ] Clinic staff compare the vaccine ordered to the packing slip and vaccines received. If there is a discrepancy or vaccines are not in proper condition upon arrival, staff alert the VFC Program within 24 hours of receipt of the vaccine shipment
- [ ] Clinic staff checks vaccine and diluent expiration dates. If any short-dated products are received, the VFC Program is notified within 24 hours of vaccine receipt.
- [ ] Clinic staff unpacks and properly stores vaccine shipments IMMEDIATELY upon arrival
    - Vaccines and diluents are stored according to manufacturer recommendations
    - Varicella containing vaccines are stored in the freezer. MMRII (Merck) may also be stored in the freezer
    - Priorix MMR (GSK) is stored in the refrigerator
- [ ] Vaccine Packing slips are maintained for both VFC and private vaccine inventory for a minimum of three years
- [ ] Staff verify that vaccine orders are “received” electronically. IRIS functionality automatically adds vaccine orders to the organization inventory and will email confirmation to the “Vaccine Delivery” contact for the origination. In addition, IRIS users will receive a pop-up message to inform users of a new delivery added to inventory

VACCINE MANAGEMENT & STOCK ROTATION (Select all that apply)

- [ ] A physical count of vaccine inventory is conducted at least once per month
- [ ] Vaccine and diluent expiration dates are checked at least once per month. Expired vaccine/diluents are removed immediately
- [ ] Vaccine stock is rotated regularly (best practice is weekly) and each time new inventory is received. Vaccines with the earliest expiration dates are moved to the front
- [ ] Clinic staff can distinguish VFC vaccine from private vaccine inventory
- [ ] Iowa VFC Program staff are notified of vaccine that will expire within three months without being used. Clinic staff should work with VFC Program staff to find an acceptable vaccine transfer location to prevent waste. Program staff can be contacted at 800-831-6293

VACCINE RETURNS and WASTAGE (Select all that apply)

Never assume vaccine is nonviable in the event of a storage and handling issue. Contact the Iowa VFC Program immediately at 800-831-6293 for instructions. VFC providers using IRIS inventory shall document vaccine loss using appropriate reasons in the registry to deduct doses from inventory.

- [ ] Nonviable vaccines are removed from storage units and labeled as “Do Not Use”
- [ ] All VFC vaccine loss is reported to the VFC program following the VFC-IRIS Nonviable Vaccine Return Instructions.
- [ ] Returnable vaccines are returned to McKesson Specialty Distribution

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Public Health

STAFFING and TRAINING (Select all that apply)

- ☐ The Vaccine Storage and Handling Plan is posted on or near the storage unit. It is reviewed and updated annually and any time there is a change in staff responsibilities
- ☐ Staff is trained on the plan and proper vaccine storage and handling. Training is renewed and documented annually or more frequently
- ☐ Primary and backup coordinators have complete the CDC's You Call the Shots training modules. Vaccine Storage and Handling and Vaccines for Children modules are completed annually.
- ☐ Staff who administer vaccines have read and understand package inserts prior to administering vaccine
- ☐ Staff who administer vaccines follow the Advisory Committee on Immunization Practices (ACIP) recommendations
- ☐ Staff have access to manufacturer package inserts for each vaccine on hand, the current ACIP Immunization Schedules and the CDC Epidemiology and Prevention of Vaccine Preventable Diseases "Pink Book"

VACCINE PREPARATION (Select all that apply)

- ☐ Vaccines are prepared in a designated area away from any areas where potentially contaminated items are placed
- ☐ Vaccines are only prepared when ready to administer
- ☐ Vaccine and diluent expiration dates are checked prior to administration
- ☐ Vaccines are only administered by the person who prepared them
- ☐ Single-dose vials (SDV) are only used one time and for one patient
- ☐ Only the number of doses indicated in the package insert are withdrawn from multidose vials (MDV)
- ☐ Partial doses from two or more vials are never used to obtain a dose of vaccine
- ☐ Manufacturer-filled syringes (MFS) are only activated (removing syringe cap and attaching needle) when ready to use
- ☐ Prefilled syringes, unused activated MFS and/or unused SDV without a protective cap are stored according to manufacturer recommendations and are wasted/returned at the end of the clinic day if not used. The manufacturer package insert is referenced for storage and handling recommendations for reconstituted vaccines.

VACCINE COORDINATORS (Select all that apply)

The primary vaccine coordinator performs the following responsibilities. The backup coordinator should be prepared to perform the same responsibilities as the primary coordinator if needed.

- ☐ Designated person(s) monitor operation of the vaccine storage units and systems as well as the overall vaccine storage and handling practices

- ☐ Designated person(s) follows routine and emergency procedures for vaccine shipments, storage and handling, transport and inventory management
- ☐ Designated person(s) sets up and maintains a monitoring/notification system during times of inclement weather or other conditions that would create an interruption of power
- ☐ Designated person(s) ensures the appropriate handling of vaccines during a natural disaster or power outage
- ☐ Designated person(s) has access to the building where vaccines are stored 24 hours per day

EMERGENCY RESPONSE GUIDEANCE AND INFORMATION

VACCINE STORAGE AND HANDLING STAFF

Primary Vaccine Coordinator:	
Backup Vaccine Coordinator:	
Additional Staff:	
Iowa Immunization Program	Phone: 800-831-6293 Fax: 800-831-6292 Email: IowaVFC@hhs.iowa.gov
Iowa VFC Nurse Clinician:	Phone:

EMERGENCY CONTACT LIST—List of emergency phone numbers, companies and contacts

Electric Power Company:
Temperature Alarm Monitoring Company:
Refrigerator Repair Company:
Party Responsible for Coordinating Backup Storage:
Emergency Generator Repair Company:
National Weather Service:

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Public Health

FACILITY FLOOR PLAN—Describe facility information and the process for entering the building and vaccine storage spaces after hours in an emergency. Attach a copy of the floor plan.

Storage unit(s) location(s):
Ingress/egress doors:
Flashlight(s) location(s):
Spare battery location(s):
Light switches:
Keys:
Locks:
Alarms:
Circuit breaker location(s):
Packing materials and location(s):
☐ Copy of floor plan attached to document or included as a supplemental document

BACKUP SUPPLIES and FACILITIES

It is important to have a backup plan to appropriately store vaccine. Make formal arrangements (memorandum of understanding) with a backup facility to maintain vaccine if primary vaccine storage equipment malfunctions or there is an extended power outage. Staff should have 24-hour access to the backup facility. Vaccine storage requirements apply to backup units. Designated primary and backup personnel must be trained to accept vaccine if it is moved. Before moving vaccine, call the backup facility to ensure there is space and personnel available to accept and manage the transfer. If the backup facility is not available, contact other facilities on the list.

Backup Facility Contact Information

Name of Facility	Address	Point of Contact	POC Phone number

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Public Health

VACCINE TRANSPORT

Vaccines should not be routinely transported. A sufficient supply of materials needed for vaccine transport of the largest inventory at any given time should be maintained for situations requiring transport. Reference Packing Vaccines for Transport during Emergencies. Only open vaccine storage unit doors when prepared to pack vaccines for transport. Take an inventory of vaccines and document actions taken to protect vaccines.

The following materials are used for vaccine transport by this facility (select all that apply):

- ☐ Portable vaccine refrigerator/freezer unit(s)—Preferred option

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- ☐ Qualified containers and packouts
- ☐ Coolant materials such as phase change materials (PCMs)

- ☐ Hard-sided insulated containers or Styrofoam **(this system should only be used in an emergency)**
- ☐ Conditioned water bottles **(this system should only be used in an emergency)**
- ☐ Insulating materials such as bubble wrap and corrugated cardboard

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- ☐ Digital Data Logger (DDL) for each transport container

Frozen vaccines

If frozen vaccines must be transported, use a portable vaccine freezer or qualified packout that maintains a temperature range of -58.0°F to +5.0°F (-50.0°C to -15.0°C). DO NOT use dry ice.

- DDLs are placed in the container as close as possible to vaccines
- Upon arrival at the destination, vaccines are immediately unpacked and stored at the recommended temperatures
- Record the time vaccines are removed from the storage unit(s) and placed in the transportation container. Temperatures are recorded for the duration of transport as well as the time vaccines are placed in a stable storage unit.

Refrigerated vaccines

If refrigerated vaccines must be transported, use a portable vaccine refrigerator or qualified packout that maintains a temperature range of 36.0° to 46.0°F (2.0° to 8.0°C).

In an emergency situation, frozen water bottles can be used as coolant packs if properly conditioned. Hold water bottles under running tap water or submerge them in a sink filled with tap water until a layer of water forming near the surface of the plastic can be seen. When the ice block inside the bottle can spin freely, the bottle is ready to be used for packing. Use appropriate insulating materials (e.g., bubble wrap) to protect vaccines from direct contact with the water bottles. Do not use frozen gel packs or coolant packs from vaccine shipments to pack refrigerated vaccines.

Immediately upon arrival at the destination, vaccines should be stored in an appropriate storage unit with a DDL. Document total transport time, the current, minimum and maximum temperatures in the transport container(s) as well as the current, minimum and maximum temperatures in the alternate storage unit(s). Vaccine storage unit temperatures should continue to be monitored while vaccines remain in the alternate storage unit.

If vaccines cannot be stored in an on-site storage unit, they should be kept in a portable vaccine storage unit and follow this guidance:

- Place a DDL as close as possible to the vaccines. Check and record temperatures hourly
- Keep the container closed as much as possible
- During off-site clinic, remove only one MDV or 10 doses at a time for preparation and administration by each person administering vaccines
- Total time for transport alone, or transport plus clinic workday should not exceed 8 hours

If vaccines were exposed to out-of-range temperatures at any time, follow temperature excursion guidance.

TEMPERATURE EXCURSION

Any temperature outside the ranges recommended in the manufacturer's package inserts is considered a temperature excursion. Identify temperature excursions quickly and take immediate action.

Notify

- Notify the primary or alternate vaccine coordinator immediately
- Label exposed vaccines "Do Not Use" and continue to store vaccines under correct temperature storage conditions. DO NOT discard the vaccines
- Keep exposed vaccines separated from unaffected vaccines and any new vaccine received
- Notify the Iowa VFC Program of the excursion

Document

Document details of the temperature excursion on the Storage and Handling Incident Response Worksheet.

- Date and time of the excursion
- Overview of the incident
- Type of storage unit(s) involved
- Storage unit(s) temperatures—current, minimum and maximum temperatures during the excursion
- Total length of time storage unit was outside of normal range
- Download of the DDL data from the excursion
- Inventory of affected vaccines and manufacturer viability status
- Name of the person completing the report

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Contact

- Contact the manufacturers of affected vaccines. Be prepared to provide DDL data so they can provide guidance on vaccine viability. If multiple excursions have occurred with any of the affected vaccines, provide the cumulative exposure time/temperatures to the manufacturers
- Contact the Iowa VFC Program to discuss recommendations and/or submit a completed Storage and Handling Incident Response Worksheet to IowaVFC@hhs.iowa.gov

Correct

- If the temperature alarm goes off repeatedly, do not disconnect the alarm until the cause has been determined
- Check the basics (power supply, unit door, DDL placement, thermostat settings, etc.)
- If the storage unit has failed or is not stabilizing, implement the vaccine storage and handling protocol for transporting vaccine to a backup unit. If alternative storage is available within the facility, transfer the vaccine to the unit. If not, contact the backup facility to notify them of a refrigerator/freezer failure and the need to store vaccine at the alternate location. Do not allow vaccines to remain in a nonfunctioning unit following a temperature excursion.
- If vaccines were moved to alternate storage units, verify primary storage units are functioning properly, and temperatures are in range before attempting to move any vaccine back. It may take two to seven days to stabilize the temperature in a newly installed or repaired refrigerator or two to three days for a freezer. Once two consecutive days of temperatures have been recorded in the recommended range, the unit is stable and ready to be used. Follow the vaccine transport procedure to transfer the vaccines back to the primary unit.

Vaccine Manufacturer Contact Information for Viability		
Manufacturer	**Phone Number**	**Online Stability Calculator or Website**
AstraZeneca	800-236-9933	https://www.astrazeneca-us.com/az-in-us/Contact-us.html
Bavarian Nordic	844-422-8274	https://bnvaccines.com
GSK	888-825-5249	https://www.gskusmedicalaffairs.com/stability-calculator.html
Grifols	888-474-3657	https://www.grifols.com/en/home
Merk	800-672-6372	https://www.merckmedicalportal.com/s/temperature-stability-calculator
Moderna	866-663-3742	https://tools.modernamedinfo.com/excursion
Novavax	844-668-2829	https://us.novavaxcovidvaccine.com/hcp
Pfizer	800-438-1985	https://www.pfizermedicalinformation.com/en-us/stability-calculator
Sanofi Pasteur	800-822-2463	https://www.sanofimedicalinformation.com/s/stability-calculator
Seqirus	855-358-8966	https://www.cslseqirus.com/products

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Public Health

VACCINE STORAGE AND HANDLING TRAINING LOG		
Staff	**Name of Training**	**Completion Date**