Facility Name:	
Effective Date:	
Reviewed By:	

VFC PIN:	
Annual Review Date:	

VACCINE STORAGE AND HANDLING PLAN

Keep this plan posted near vaccine storage units.

This 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 available at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling- toolkit.pdf for the most current guidance and best practices regarding vaccine storage and handling. Additional details and VFC requirements are outlined in Iowa's Vaccines for Children Program Operations Guide.

DIGITAL DATA LOGGERS (DDL)CALIBRATION DETAILS

Data Logger ID	Current Calibration Date	Next Calibration Due Date	R – Refrigerator F – Freezer U – Ultra Cold B – Backup

VACCINE MANAGEMENT COORDINATOR

Each VFC provider must designate one staff member as the primary vaccine coordinator and at least one back-up coordinator who is able to perform the same responsibilities as the primary vaccine coordinator. These positions shall be responsible for oversight of vaccine management, including vaccine storage and handing, within the facility and serve as the VFC contact for the office.

VFC providers must annually train ALL staff with vaccine management responsibilities on proper vaccine storage and handling procedures. Staff training must be documented.

ROUTINE VACCINE STORAGE AND HANDLING GUIDELINES

STORAGE REQUIREMENTS

- ☐ Vaccine storage units maintain recommended unit temperature ranges. The recommended temperatures are posted on the units:
  - ☐ Refrigerator: 36.0° through 46.0°F or 2.0° through 8.0°C Freezer: -
  - ☐ 58.0° through +5.0°F or -50.0° through -15.0°C
  - ☐ Ultra Cold: -112.0° through -76.0°F or -80.0° through -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 at 36.0° through 46.0°F or 2.0° through 8.0°C
- ☐ Digital data loggers (DDL) are present in each unit that stores vaccines (refrigerator and freezer)
  - ☐ A digital data logger (DDL) with continuous temperature monitoring, recording capability and a current valid Certificate of Calibration Testing must be placed in the refrigerator and freezer unit. The DDL must be 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's door
    - ☐ Current, minimum, and maximum temperature display
    - ☐ Logging interval (or reading rate) programmed to measure and record temperatures at least every 30 minutes
    - ☐ 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: -112.0° through -76.0°F or -80.0° through -60.0°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. Calibration should be done every 2-3 years or according to manufacturer's recommendations.

    Each certificate of calibration must include:
    - Model/device name 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 back-up digital data logger is readily available. The backup DDL meets all of the above requirements and has a <u>different</u> calibration date than the primary DDL's

☐ To stabilize temperatures, water bottles are kept on the top shelf, floor, and in the door racks. (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 center of the unit(s) in 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 in 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 the 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/SAFEGUARDS

☐ Vaccines are stored according to manufacturer recommendations in one of the following:

- A purpose-built or pharmaceutical grade unit
- A household-grade stand alone or combination unit (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 to store frozen vaccines.)

☐ Dorm-style/bar style refrigerator/freezer units are *never* used to store vaccines

☐ Warning signs (e.g., Do Not Unplug) are posted on vaccine storage units and at the outlet fuses

☐ Circuit breakers supporting vaccine storage units are clearly marked

☐ Safety lock plugs or outlet covers are used to prevent the unit from being unplugged

☐ The vaccine storage unit is not plugged into a GFI outlet, extension cord or power strip

☐ Each vaccine storage unit is directly plugged into a wall outlet; only one storage unit per electrical outlet

☐ Vaccine storage unit doors close securely and are free from defects

☐ Vaccine storage units are large enough to store vaccine supply at all times without overcrowding

☐ Routine maintenance is completed for all units (check doors seals, clean coils and other components per manufacturer directions, defrost manual-defrost freezers, clean interior of units, test backup generator, etc.)

TEMPERATURE MONITORING

- ☐ DDL(s) are present in each storage unit for temperature monitoring as outlined in 'Storage Requirements' section
- ☐ Storage unit(s) minimum and maximum temperatures are checked and recorded on a temperature log at the start of each work day along with staff initials and time of reading The storage unit(s)
- ☐ current temperatures are checked and recorded on a temperature log twice daily (at the start and end of the workday) along with staff initials and time of readings
- ☐ Storage temperature logs are maintained for at least 3 years for each unit either in electronic or paper format (If a digital data logger has the capability to annotate an electronic temperature check with the time and initials of the person checking the temperature, it is not necessary to manually log the temperature checks at each temperature check)
    - ☐ The designated person reviews temperature logs at least weekly to ensure proper temperature recording and takes action if out of range temperatures are found on the logs during review
    - ☐ The data logger is 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 outside of the recommend range are found, immediate action should be taken as outlined in the 'Temperature Excursion' section

VFC VACCINE ORDERING

- ☐ Before placing VFC vaccine orders, current inventory/expiration dates are reviewed and seasonal events and specialty clinics are considered
- ☐ Clinic staff is trained regarding the VFC vaccine ordering process and submits orders through Iowa's Immunization Registry Information System (IRIS)
- ☐ Clinic staff places VFC orders based on the facility's assigned ordering frequency Clinic staff
- ☐ Reviews the recommended order quantities prior to placing VFC orders considering the total amount of vaccine needed including both combination and single antigen presentations
- ☐ Clinic staff makes efforts to not over-order or stockpile vaccine, while maintaining adequate inventory to prevent missed opportunities to vaccinate
- ☐ An adequate inventory of VFC and private vaccine (if applicable) is maintained to eliminate occurrences of borrowing between VFC and private inventories

RECEIVING VACCINE

- ☐ 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 a week other than Monday and is available for at least four consecutive hours during the day
- ☐ Clinic staff checks the cold chain monitor included in the shipment (device used to monitor vaccine temperature during transport) ensuring vaccine was maintained at the appropriate temperatures during shipping

- ☐ When reviewing packing slips for frozen vaccines, the maximum time vaccines can be in transit based on shipment date is checked and verified
- ☐ Clinic staff compares the vaccine received to the packing slips and will alert the VFC Program if vaccine doses do not match the invoice or if the vaccines are not in proper condition upon arrival
- ☐ Clinic staff checks vaccine/diluent expiration dates to assure no expired or soon to expire products have been received
- ☐ Clinic staff ensures vaccine shipments are unpacked and stored properly **IMMEDIATELY** upon arrival
    - Vaccines and diluents are stored according to manufacturer recommendations
    - Varicella containing vaccines and MMRII (Merck) are 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
- ☐ VFC vaccine orders are "received" electronically. IRIS functionality automatically adds vaccine orders to the organization inventory and will email the Vaccine Delivery contacts within a provider organization to inform the organization a vaccine order has been sent and has been added to inventory. In addition, IRIS users at the organization will receive a pop- up message to inform users a new vaccine order was added to inventory

VACCINE MANAGEMENT/STOCK ROTATION

- ☐ A physical count of vaccine inventory is conducted at least monthly
- ☐ Vaccine and diluent expiration dates are checked at least monthly. Expired vaccines/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 is able to distinguish VFC vaccine from private vaccine inventory
- ☐ VFC vaccine that will not be used and will expire within 2-3 months is reported to the Iowa VFC Program at 1-800-831-6293

VACCINE RETURN/WASTAGE

Never assume vaccine is nonviable in the event of a storage or handling issue. Contact the Iowa VFC Program immediately (1-800-831-6293) for instructions regarding VFC vaccine. VFC providers using IRIS inventory shall document vaccine loss using appropriate reasons provided in the registry to deduct doses from inventory.

- ☐ Nonviable vaccines are removed from storage units and labeled as "nonviable vaccine-do not use"
- ☐ All VFC vaccine loss is reported to the VFC program (see VFC-IRIS Nonviable Vaccine Return Instructions) for directions
- ☐ Spoiled/expired VFC vaccine doses are returned to McKesson Specialty Distribution

STAFFING/TRAINING

- ☐ A Vaccine Storage and Handling plan is posted on or near the storage unit and 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 documented (minimum of annually)
- ☐ The primary and back-up coordinators have completed the CDC's web-based You Call the Shots modules *Vaccine Storage and Handling* and *Vaccines for Children* (https://www.cdc.gov/vaccines/ed/youcalltheshots.html)
- ☐ 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 has access to manufacturer's package inserts for each vaccine on hand, the most current ACIP Immunization Schedules, and the CDC Epidemiology and Prevention of Vaccine Preventable Diseases (Pinkbook)

VACCINE PREPARATION

- ☐ 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 them
- ☐ Vaccine and diluent expiration dates are checked prior to administration
- ☐ Vaccines are only administered by the person that prepared them
- ☐ Single-dose vials (SDV) are only used one time 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 unused SDV without a protective cap are stored according to manufacturer recommendations and are discarded at the end of the clinic day if not used. The manufacturer package insert is referenced for storage and handling recommendations of reconstituted vaccines

VACCINE COORDINATORS

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.

- ☐ The designated person(s) monitors the operation of the vaccine storage units and systems, as well as the overall vaccine storage and handling practices
- ☐ The designated person(s) follow routine and emergency procedures for vaccine shipments, storage and handling, transport, and inventory management
- ☐ The 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 The
- ☐ designated person(s) ensures the appropriate handling of the vaccine during a disaster or power outage
- ☐ The designated person(s) has access to the building where vaccines are stored 24 hours per day

EMERGENCY RESPONSE GUIDELINES

VACCINE STORAGE AND HANDLING STAFF

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

EMERGENCY CONTACT LIST

List of emergency phone numbers, companies, and points of contact:

Electric Power Company:
Temperature Alarm Monitoring Company:
Refrigerator Repair Company:
Transportation to Back-up Storage:
Emergency Generator Repair Company:
National Weather Service:

FACILITY FLOOR PLAN

Describe, when necessary, how to enter the building and vaccine storage spaces in an emergency if closed or after hours. Include a simple floor diagram (does not need to be a blueprint) and the locations of the following:

☐ Storage units:
☐ Doors:
☐ Flash lights:
☐ Spare batteries:
☐ Light switches:
☐ Keys:
☐ Locks:
☐ Alarms:
☐ Circuit breakers:
☐ Packing materials:

☐ Floor plan (copy and paste diagram here or attach to the document):

BACK-UP SUPPLIES/FACILITIES

It is important to have a back-up plan to appropriately store vaccine. Make formal arrangements (memorandum of understanding) with a backup facility to maintain vaccine if vaccine storage equipment malfunctions or there is an extended power outage. Staff should have 24 hour access to the back-up facility. Vaccine storage requirements apply to back-up units. Train a designated person and backup person at the facility to accept vaccine if it must be moved. Before moving the vaccine, call the location to ensure the facility is available to store the vaccine (e.g., not damaged due to storms). If the back-up facility is not available contact the other facilities on the backup facility list.

Back-up Facilities Contact Information

Name of Facility	Address of Back-Up Location	Point of Contact Name	Point of Contact Phone Number Work/Home/Cell

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 that require 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 the vaccines.

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

☐ vaccine refrigerator/freezer units (preferred option)

☐ 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 for each transport container

Frozen vaccines: If frozen vaccine must be transported, use a portable vaccine freezer unit or qualified packout that maintains temperatures between: -58.0° through +5.0°F or -50.0° through -15.0°C. DO NOT use dry ice.

- Place a DDL in the container as close as possible to the vaccines
- Immediately upon arrival at the destination, unpack the vaccines and place them in a freezer at the recommended storage temperatures.
- 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.

Refrigerated vaccines: 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 in a sink filled with tap water until a layer of water forming near the surface of the plastic can be seen. Once 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(s) with a DDL. Document total transport time, the current, minimum, and maximum temperatures in the transport container(s) and the current, minimum, maximum temperatures in the alternate storage unit(s). Vaccine storage unit(s) temperatures should continue to be monitored as required as long as vaccine remains in the unit (Reference 'Temperature Monitoring' Section)

If vaccines cannot be stored in an on-site storage unit, they should be kept in the portable vaccine storage unit:

- Place a DDL as close as possible to the vaccines, and check and record temperatures hourly
- Keep the container closed as much as possible

- For off-site clinic use, remove only one multi-dose vial or 10 doses at a time for preparation and administration by each person administering vaccines
- The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 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". Continue to store vaccines under correct temperature storage conditions and DO NOT discard the vaccines
- Keep exposed vaccine separated from unaffected vaccine and any new vaccine received
- Notify the Iowa HHS Immunization Program to report the excursion event

Document

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

- Date and time of the excursion
- Overview of the incident
- Type of storage unit (s)
- Storage unit(s) temperature-current and minimum/maximum temperatures during the time of the event
- Total length of time storage unit(s) was outside of normal range
- Inventory of affected vaccines
- Name of person completing the report

Contact

- Contact the manufacturers of the 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 this cumulative exposure time/temperatures to the manufacturers.
- Contact the Iowa HHS Immunization Program to discuss recommendations and/or submit completed Storage and Handling Incident Response Worksheet

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(s), DDL placement in unit, thermostat settings)
- If the storage unit has failed or is not stabilizing, implement the vaccine storage and handling protocol for transporting vaccine to a back-up unit. If alternative storage is available within the facility, transfer vaccine to that storage unit. If not, contact the backup facility to notify them of a refrigerator/freezer failure and the need to store vaccine at the backup 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 2 to 7 days to stabilize the temperature in a newly installed or repaired refrigerator or 2 to 3 days for a freezer. Once 2 consecutive days of temperatures have been recorded within the recommended range, the unit is stable and ready to be used. Follow the 'Vaccine Transport' procedure to transfer vaccines back to the primary unit.

Vaccine Manufacturer Contact Information for Excursions		
Manufacturer	**Phone number**	**Online Stability Calculator or Website**
AstraZeneca	1-800-236-9933	https://www.astrazeneca-us.com/az-in-us/Contact-us.html (general manufacturer website)
GlaxoSmithKline	1-888-825-5249	https://www.gskusmedicalaffairs.com/stability-calculator.html
Grifols	1-888-474-3657	https://www.grifols.com/en/home (general manufacturer website)
Johnson & Johnson - Janssen	1-800-565-4008	https://vaxcheck.jnj/
Merck	1-800-672-6372	https://www.merckmedicalportal.com/s/temperature-stability-calculator
Moderna	1-866-663-3742	https://tools.modernamedinfo.com/excursion
Novavax	1-844-668-2829	https://us.novavaxcovidvaccine.com/hcp (general manufacturer website)
Pfizer	1-800-438-1985	https://www.pfizermedicalinformation.com/en-us/stability-calculator
Sanofi Pasteur	1-800-822-2463	https://www.sanofimedicalinformation.com/s/stability-calculator
Seqirus	1-855-358-8966	https://www.cslseqirus.com/products (general manufacturer website)

VACCINE STORAGE AND HANDLING TRAINING LOG

Staff	Name of Training	Training Date