2025

Immunization Division

Vaccine Management Plan

Office and Vaccine Coordinator Information

This plan must be reviewed and updated annually or when key staff change. This plan must be dated and signed by the person responsible for the plan's content.

Office/Practice Name	
VFC PIN (e.g. M00L00)	
Location Address	
Phone Number	
Fax Number	

Medical Director/Signatory

Name	
Email	
Phone Number	

Primary Vaccine Coordinator

Name	
Email	
Phone Number	

Back-up Coordinator

Name	
Email	
Phone Number	

Emergency Contact

This contact should have 24-hour access to the building, in case of emergency.

Name	
Phone Number	

This form was completed by _____ on _____.

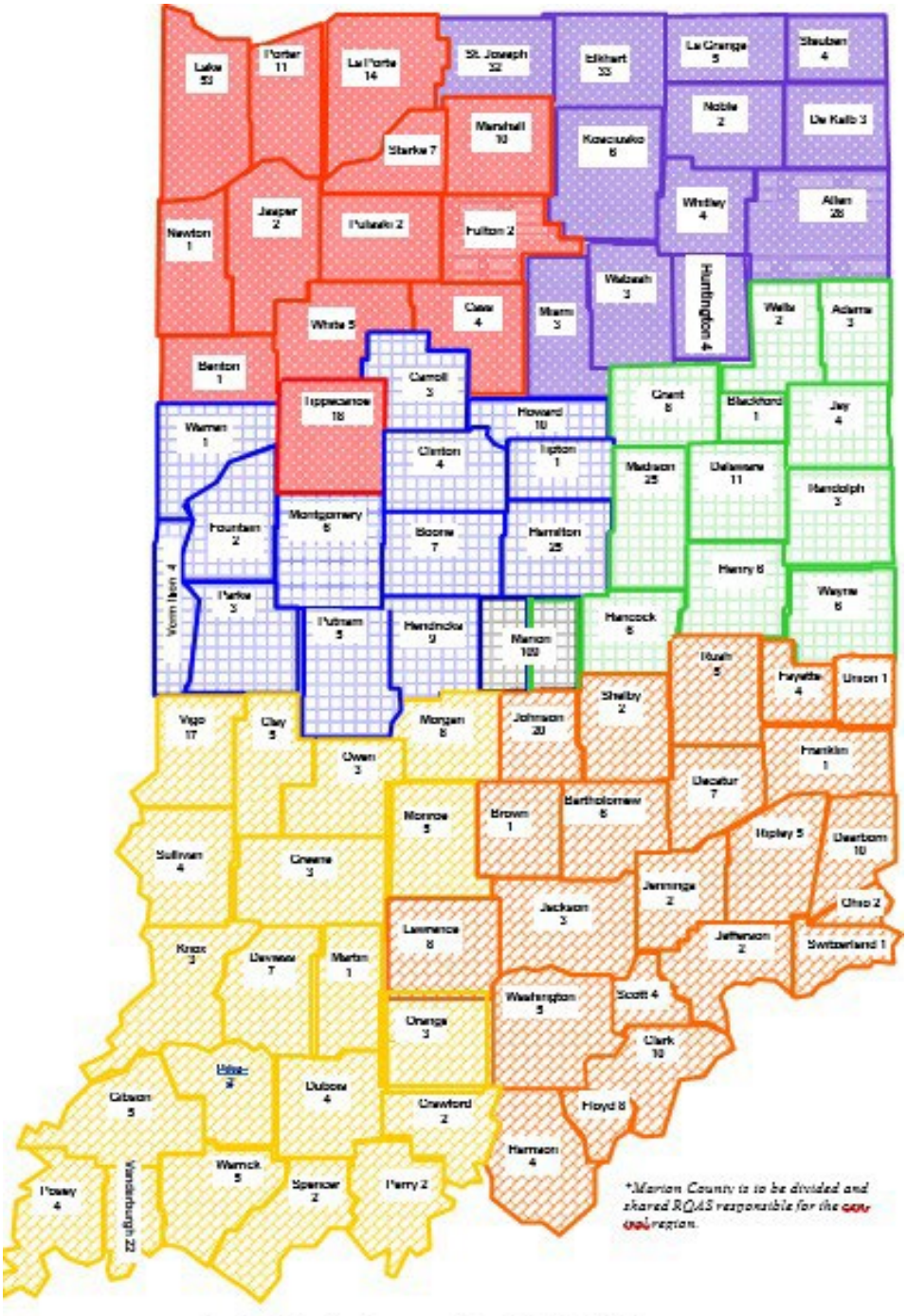
Signature Date

Contents

Signed Provider Agreement

Place a copy of your facility's signed provider agreement to receive publicly supplied vaccine here.

Immunization Service Delivery Map



Regional Quality Assurance Specialists (**RQAS**)
Vaccine Ordering and Accountability (**VAM**) Specialists
Immunization Division Service Delivery Map, January 2024

Immunization Service Delivery Map
Key Personnel

Maternal Immunization and Perinatal Hepatitis B Coordinator Ondreya Witmer, 317-518-0726 owitmer@health.in.gov Covers birthing hospitals and independent pharmacies for the whole state	**Replacement Model Specialist** Holly Carson, 317-726-7426 hcarson@health.in.gov Covers ordering for birthing hospitals, pharmacies, and other providers in the replacement program for the whole state
RQAS Coordinator: Diana Taylor, 317-416-5929 ditaylor@health.in.gov	**VAM Coordinator:** Tracy Brunette, 317-606-5091 tbrunette@health.in.gov
North A	**Central D**
RQAS: Adriene Clingaman, 765-726-1561 aclingaman@health.in.gov VAM: Melissa Sailors, 317-376-9783 msailors@health.in.gov	RQAS: Carla Cly-Williams, 317-439-6370 cclywilliams@health.in.gov VAM: Nancy Mack, 317-233-2320 nmack@health.in.gov
North B	**South E**
RQAS: Mindy Dixson, 317-914-5286 Mdixson2@health.in.gov VAM: Melissa Sailors, 317-376-9783 msailors@health.in.gov	RQAS: Tom Keller, 317-519-3052 tkeller@health.in.gov VAM: Victoria Bailey, 463-224-2238 vbailey@health.in.gov
Central C	**South F**
RQAS: Ashlei VanBuskirk, 463-271-1238 avanbuskirk@health.in.gov VAM: Nancy Mack, 317-233-2320 nmack@health.in.gov	RQAS: Milly Jines, 317-519-2611 mjines@health.in.gov VAM: Victoria Bailey, 463-2238 vbailey@health.in.gov

Overview

The Centers for Disease Control and Prevention (CDC) requires all Vaccines for Children (VFC) providers to develop, maintain, and implement a Vaccine Management Plan with detailed and up-to-date standard operating procedures for routine and emergency vaccine management. The Indiana Department of Health (IDOH) Immunization Division has prepared this document as a template to assist your office with this requirement. Please refer to IDOH VFC Program Policies for supplemental information and guidance.

For access to the most recent policies, documents and information, visit https://www.in.gov/health/immunization/.

Vaccine Coordinator Roles and Responsibilities

VFC providers are required to designate a primary vaccine coordinator and at least one back- up vaccine coordinator for each facility. **Notify the IDOH regional quality assurance specialist (RQAS) immediately of any changes in the medical director, primary vaccine coordinator, or back-up vaccine coordinators.** All coordinators must be fully trained on routine and emergency standard operating procedures (SOPs) for vaccine ordering, storage, handling, transport and inventory management.

Regional Quality Assurance Specialist

Name	
Email	
Phone Number	

Regional Ordering and Accountability Specialist

Name	
Email	
Phone Number	

IDOH Immunization Division

Always include your VFC PIN for reference.

Email	vaccine@health.in.gov
Phone Number	1 (800) 701-0704

Vaccine Coordinator Responsibilities

The vaccine coordinator is responsible for overseeing all vaccine management within the facility, including:

- Developing and maintaining this Vaccine Management Plan
- Monitoring all vaccine storage and handling and vaccine administration practices in the facility, including responding to and documenting all temperature excursions and reporting them to the IDOH Staff Representative
- Overseeing vaccine ordering and notifying the IDOH Staff Representative if vaccines will expire before they are administered
- Ensuring and documenting annual vaccine management training for designated staff as well as training new staff upon hire
- Participating in and documenting completion of annual training on VFC requirements
- Storing all required documentation for three years

Vaccine Storage and Handling

- Ensure the vaccine cold chain is maintained at all times.
- Ensure refrigerator and freezer units that house VFC vaccine meet CDC requirements.
- Ensure storage unit digital data loggers (DDLs) and/or continuous temperature monitoring system meet CDC requirements.
- Oversee proper receipt and storage of all vaccine shipments, including training any office and front desk staff on storage and handling practices in the event they encounter vaccine shipments.
- Monitor all VFC inventory expiration dates and rotate vaccine stocks to ensure soon-to-expire vaccines are used first.
- Ensure VFC and privately purchased vaccine stocks are clearly separated.
    - Have a tracking system in place to record any doses that are accidentally borrowed from VFC and ensure all VFC doses are replaced with private-purchased vaccines in a timely manner.
- Place "DO NOT UNPLUG" stickers by the wall outlets into which storage units that house VFC vaccine are plugged.
- Circuit Breaker boxes should be clearly marked with the associated outlet and emergency contact information if the breaker box is tripped and/or there is scheduled maintenance.

Daily Temperature Monitoring and Recording

- Document the minimum and maximum temperatures of each storage unit at the start of each workday.
- Record the current storage unit temperature twice daily on IDOH temperature logs.
- Maintain temperature monitoring devices, including a back-up device, and ensure they all have current certificates of calibration.
- Download and review DDL reports each work week, and report temps to IDOH as requested.
- Maintain storage equipment, including ensuring units are properly cleaned and serviced at all times.

Vaccine Ordering and Accountability

- Submit vaccine orders via the Vaccine Ordering Management System (VOMS) in the electronic Immunization Information System (IIS) registry CHIRP (Children and Hoosiers Immunization Registry Program).
- Electronically reconcile VFC vaccine inventory monthly and submit via CHIRP.
- Account for all wasted/expired/spoiled/borrowed vaccines in CHIRP and complete/submit all associated documentation forms to the IDOH Immunization program.
- Ensure all vaccine orders are received electronically in CHIRP.

Emergency Situations

- Follow all protocols for protecting vaccines in emergency situations such as power outages, natural disasters, and equipment failure.
- Respond and manage all temperature excursion events.
- Follow all vaccine transport guidance.

VFC Programmatic Tasks

- Participate in all program compliance site visits with an IDOH Staff Representative, which may be scheduled or unannounced.
- Complete and submit annual provider recertification.

Annual Training Requirements

- Annually, primary and back-up VFC coordinators must complete the VFC Provider Annual Training on LMS Invest. This can be found on the CHIRP Homepage.

LMS Training

Annual Staff Training and Documentation

The **VFC Provider Annual Training** module in LMS INvest must be completed each year by the primary and backup vaccine coordinators. It is recommended that all staff who handle vaccines complete this training. Please do the training labeled VFC Provider Annual Training. You Call the Shots will not count towards your annual training requirement.

Facilities with an Immunization Quality Improvements for Providers (IQIP) visit may be asked to complete other forms of education.

Training Documentation

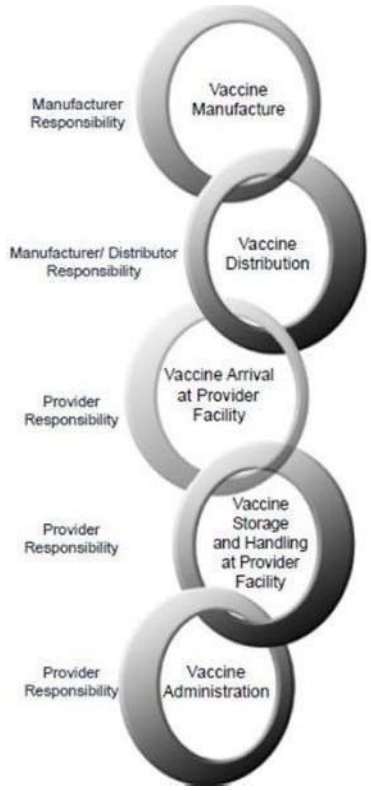
Staff Name	LMS Training Date	Additional Education (optional)

Vaccine Storage and Handling Practices

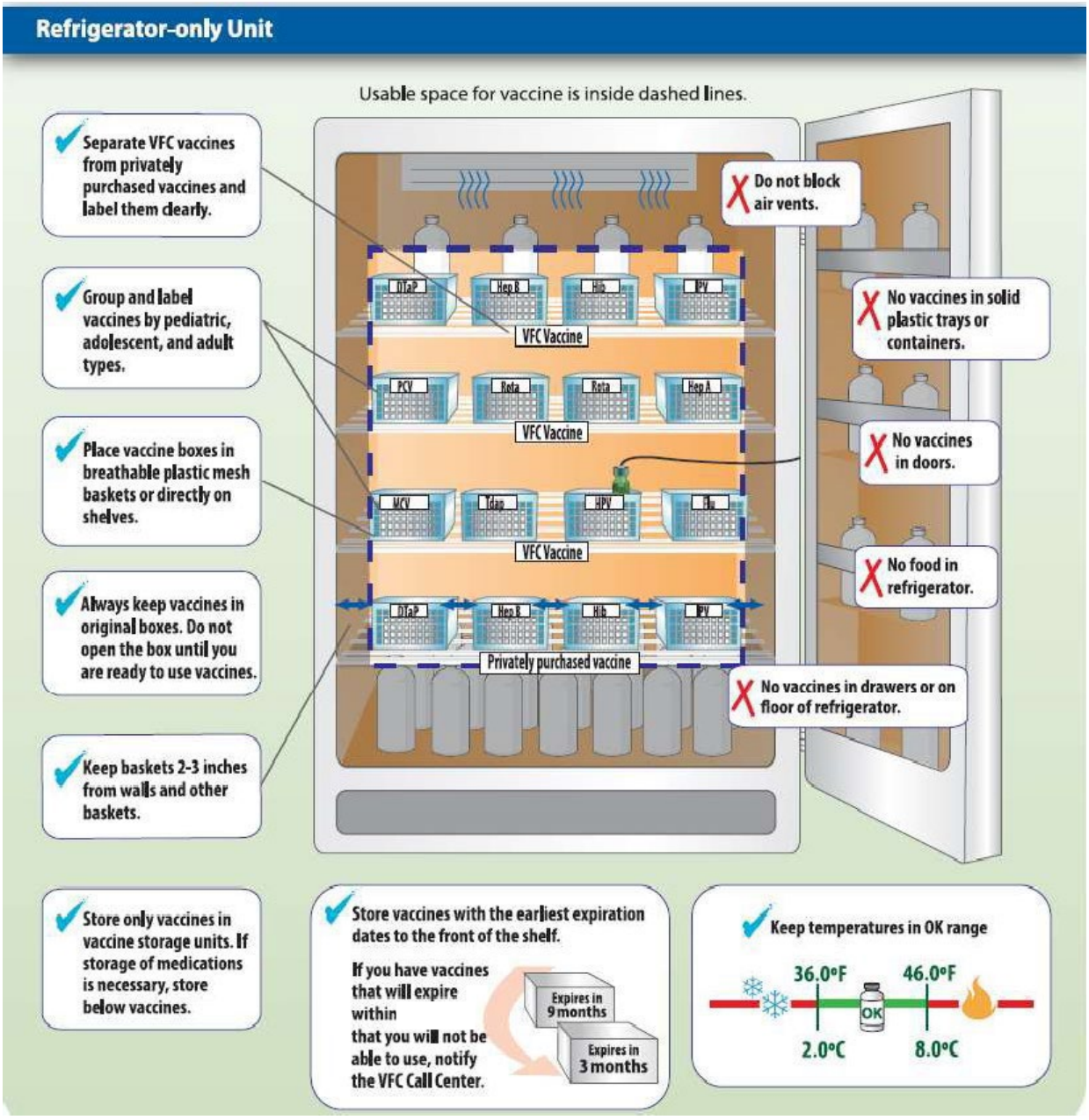
All vaccine storage and handling practices are in place to ensure the vaccine cold chain is maintained. The cold chain begins at the manufacturing plant, includes delivery to and storage at the provider facility, and ends with the administration of vaccine to the patient. Too much exposure to heat, cold or light at any step in the cold chain can result in a loss of vaccine potency. Once potency is lost, it cannot be restored.

Storage and Handling Requirements

- Stand-alone storage units that maintain correct temperatures at all times.
    - Refrigerator temperature between 36°F and 46°F (2°C and 8° C); aim for 40°F (4°C)
    - Freezer temperature between -58°F and +5°F (-50°C and -15°C); aim for 0°F (-17°C)
    - Water bottles in storage units-against walls, in the back, on the floor- to help stabilize temperatures
    - Needs to have shelves for vaccine placement
    - NO food or drinks in the storage units
    - NO vaccine storage in the unit door, on the floor, and/or under the cooling vents of a storage unit
    - NO expired vaccine in unit
- Digital data loggers (DDLs) with continuous monitoring capabilities and a current, valid each clinic.
    - Must have a glycol or other buffered solution-encased probe
    - Probe must be placed in the central area of the storage unit
    - Record DDL minimum and maximum temperatures once daily at the start of the workday
    - Download, review and store digital reports once a week; reset DDL memory at this time
    - Record point-in-time temperature readings twice daily on standard temperature logs
    - If vaccines are stored at ultra-cold temperatures, the DDL must be calibrated for ultra cold temperatures
- DO NOT UNPLUG signs by the electrical outlets into which the units are plugged
- WARNING-EXPENSIVE VACCINE IN STORAGE signs on the circuit breaker with emergency contact info and the breaker numbers listed; outlet breaker connected to the units clearly marked inside the box.



Routine Refrigerator Management



Routine Freezer Management

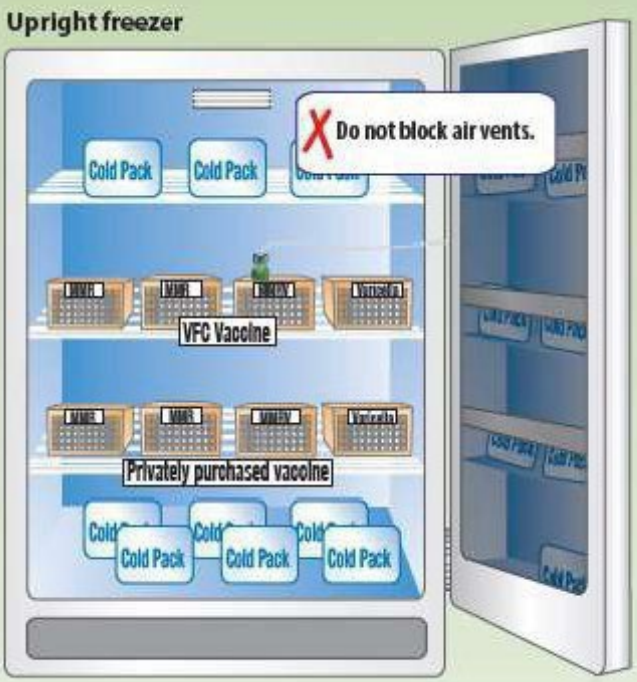
A carefully organized freezer helps protect vaccines and facilitates vaccine inventory management. Freeze MMR, MMRV, Varicella, and Zoster vaccines.

- Separate the VFC vaccine supply from privately purchased vaccine and label them clearly.
- Group and label vaccines by pediatric, adolescent, and adult types.
- Place vaccine boxes in breathable plastic mesh boxes or directly on shelves.
- Always keep vaccines in their original boxes. Do not open the box until you are ready to use the vaccine.
- Keep baskets 2-3 inches from walls and other baskets.
- Store vaccines with the earliest expiration dates to the front of the shelf.

  If you have vaccines that will expire in 3–6 months that you will not be able to use, notify the VFC Call Center.

- Keep temperatures 5.0°F or colder.

Upright freezer



Chest freezer

Routine Power Supply Management

Protect plug and outlet

Plug in vaccine storage unit to a nearby outlet.

Secure plug with a guard/cover.

Post "Do Not Unplug" signs near outlet.

Always avoid disruption of power

Do not use extension cords or power strips with an ON/OFF switch.

Never unplug the vaccine refrigerator or freezer.

Do not use outlets that are controlled by wall switches.

Do not use outlets that have built-in circuit switches (they have red reset buttons).

Label fuses and circuit breakers. Post a sign to alert the Vaccine Coordinator any time the power goes out.

Vaccine Storage Unit Locations and Maintenance

Maintenance and Repair

Company Name	
Phone Number	

Unit Locations and Maintenance Log

Unit Type	Location ID	Brand	Model	Dates of Repair
Refrigerator				
Refrigerator				
Refrigerator				
Freezer				
Freezer				
Freezer				

Temperature Monitoring Device List and Maintenance

Calibration Company/Laboratory

Company Name	
Contact Name	
Phone Number	

Locations

Completed Temperature Logs	
Certificates of Calibration	
Back-up Data Logger	

Device List

Digital Data Logger or Continuous Monitoring System	Device Model/Serial No.	Primary or Back-up?	Calibration Expiration Date	Alarm Setting Low	Alarm Setting High

Calibration Certificates

Place a copy of your facility's current calibration certificates here.

Vaccine Ordering Procedures

- All vaccine orders are submitted through the Vaccine Ordering Management System (VOMS) in CHIRP
    - Providers will be ordering influenza through VOMS. We have discontinued the use of paper influenza order forms.
- At minimum, providers should order enough vaccine for a four-week period, but no more than three months.
    - At the time of vaccine order placement:
        - Providers must ensure contact information and delivery hours are correct for the next three weeks to ensure accurate and prompt vaccine delivery (e.g. if your office will be closed on any day in the coming three weeks, or open for less than four (4) hours, uncheck that day as an option when placing your order).
        - Providers must submit their inventory monthly in VOMS
            - All vaccines administered must be entered into CHIRP prior to inventory reconciliation, via manual or Electronic Medical Record (EMR) entry.
    - Non-frozen vaccine orders typically arrive 7 to 10 days after the order has been approved in VOMS.

Frozen vaccine ships directly from the manufacturer (Merck) and will arrive separately from refrigerated vaccine. Orders may arrive up to 14 days after the VOMS approval date.

Vaccine Receiving, Documentation Procedures

The primary and/or back-up coordinator must be immediately notified if any vaccine shipment arrives. Coordinators must immediately unpack, store, and document vaccines and diluents upon receipt.

Actions must include:

- Examining the shipping container and vaccine vials for signs of physical damage
- Comparing the contents of the container to the packing list to be sure they match
    - **If there is a discrepancy with the order, provider must immediately notify the IDOH Immunization Division at 1 (800) 701-0704**.
- Making sure lyophilized (freeze-dried) vaccines came with the correct type and quantity of diluents
- Checking both vaccine and diluent expiration dates to ensure none are expired or soon-to-expire products
- Checking the cold chain monitor (CCM) for any indication of a temperature excursion during transit
- Receiving vaccine order via VOMS so that it populates your online inventory before staff begin using it.

WITHIN TWO HOURS OF VACCINE DELIVERY:

If any damage, excessive shipping time or cold chain breach is suspected, notify the IDOH Immunization Program at 1 (800) 701-0704.

Vaccine Inventory Control Procedures

- Ensure proper vaccine handling and preparation practices
    - Vaccines should be prepared immediately prior to administration.
    - Reconstitute lyophilized vaccine with the diluent that came with the vaccine-nothing else.
    - Always check expiration dates prior to preparing the vaccine (and its diluent).
    - A single-dose vial contains one dose and should only be used for one patient.
    - A multi-dose vial is intended only for the number of doses indicated in the manufacturer's insert and should not be punctured more than the indicated times.
    - In the event of a "drawn but not used" vaccine:
        - Label the vaccine with type, lot number, date/time prepared, and initials of the preparer, and place into the appropriate storage unit (refrigerator or freezer).
        - Discard any refrigerated, pre-drawn doses no later than the end of the workday.
        - Varicella-containing products must be used within 30 minutes of reconstitution.
- Monitor multi-dose vial use
    - IPV multi-dose vials can be used to their expiration date and do not have to be discarded after 28 days of opening.
- Monitor vaccine inventory expiration dates
    - With each vaccine shipment, organize storage unit so that vaccine with the closest expiration date is placed in front to be used first.
    - Conduct a patient reminder/recall for vaccine types that are soon-to-expire.
    - If you have vaccine that will expire within 90 days (three months) that your office does not anticipate using, and you have conducted a reminder/recall, notify your IDOH staff representative to inquire about a possible transfer to another VFC provider.
- Minimize VFC vaccine borrowing
    - VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory.
    - Borrowing between inventory stocks should be rare.
    - Documentation must occur when any vaccine is borrowed regardless of inventory origin (e.g. VFC to Private or Private to VFC).
    - The Borrowing Report is the only form of acceptable documentation, and it must specify an approved reason for vaccine borrowing. The form must be submitted within 30 days of borrowing via email vaccine@health.in.gov or fax 317-233-3719.
    - Approved borrowing reasons:

        - Vaccine shipment delay (public or private) Vaccine not useable on arrival (public or private)
        - Ran out of vaccine between orders, not due to shipping delays (public or private)
        - Short-dated vaccine from one stock used on a patient with the opposite eligibility (public or private)
        - Accidental use of vaccine from one stock on a patient with the opposite eligibility (public or private)
        - Replacement of private dose with VFC when insurance plan did not cover vaccine (public)
    - When borrowing occurs, funding source integrity needs to be maintained both when the vaccine is originally borrowed and when stock is repaid.
    - The funding sources for borrowed and replaced doses will need to be adjusted in VOMS.
        - Quick reference guides are located on the IDOH website https://www.in.gov/health/immunization/.
    - **Note:** Providers may use private stock seasonal influenza vaccine to vaccinate VFC- eligible children if VFC seasonal influenza stock is not yet available. Those private stock doses used on VFC- eligible children can later be replaced when VFC stock becomes available. This one-directional borrowing exception is unique to seasonal influenza vaccine.

VFC providers must offer the same vaccine formulations in both private and public stock.

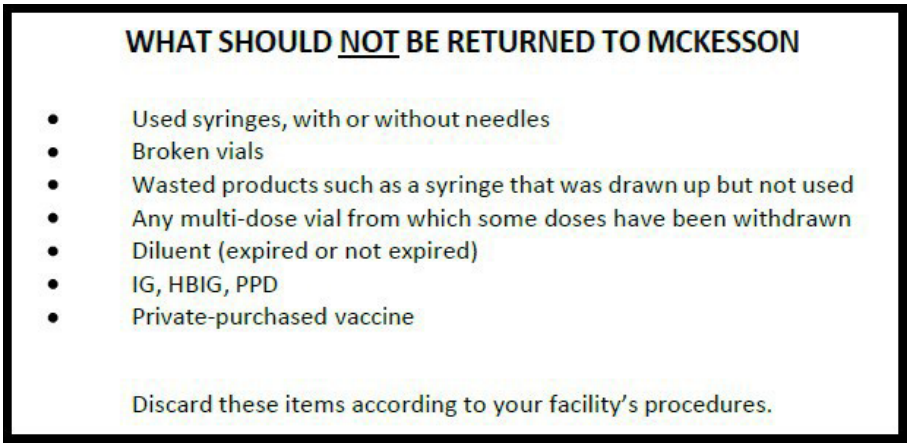
Vaccine Loss Management Procedures

All VFC providers are required to document and report all incidents of vaccine loss and wastage. When managing expired, spoiled or wasted vaccine, providers must:

- Remove the vaccines from any storage unit that stores viable vaccines.
- Label vaccines DO NOT USE.
- Document wasted or expired vaccines in VOMS.
    - All returns must be completed and documented in VOMS within six months after the product expiration or waste date.

Expired Vaccine

- ALL expired vaccine must be returned.
- Primary vaccine coordinators will receive a McKesson return label via email within 30 days of reporting the return in VOMS.



VFC Eligibility and Insurance

Patients must be screened for VFC eligibility at each visit. **Patients over the age of 19 are ineligible.**

Patient Status	VFC Eligible	IIS Category	IIS Eligibility Code	IIS Funding Source
American Indian or Alaskan Native (AI/AN) as defined by the Indian Health Care Improvement Act (25 U.S.C 1603-13)	Yes	AI/AN	V04	VXCI
Uninsured • Does not have health insurance • Enrolled in a Healthcare Sharing Ministry (i.e., MediShare, Liberty Healthshare, etc.)	Yes	Uninsured	V03	VXCI
Underinsured • Has insurance that does not cover vaccine • Served at a Federally Qualified Health Center (FQHC), Rural Health Center or deputized local health department (LHD)	Yes	Underinsured	V05	VXCI
Other • Has insurance that does not cover vaccine • Served at a non-FQHC/LHD VFC provider location	Yes	Underinsured	V05	VXCI
Insured with Private Insurance • Enrolled in private insurance plan	No	Ineligible for VFC	V01	PHC70
Medicaid* • Enrolled in Traditional Medicaid • Enrolled in Hoosier CareConnect (Full Medicaid of Package A)	Yes	Medicaid	V02	VXCI

• Enrolled in Hoosier Healthwise Package A Package A is not listed on the card and can only be determined via the Provider Healthcare Portal. • Enrolled in CHIP Medicaid Package C				

Billing

VFC-eligible Patients

- Cannot bill for the cost of the vaccine
- Can bill administration fee up to $20.32 per dose
- May issue only a single bill within 90 days
- Cannot send to collections for unpaid administration fees

Ineligible Patients

- Bill according to plan guidelines

* Indiana Family Services (FSSA) offers several different programs and services under the Indiana Health Coverage Programs (IHCP). Each IHCP member is issued a number referred to as the Member ID assigned by FSSA Division of Family Resources (DFR). The type of card received depends on the IHCP program in which the member is enrolled. Providers are required to verify member eligibility on the date of service via the Provider Healthcare portal. **Providers that fail to verify eligibility are at risk of claims being denied due to membership ineligibility or coverage limitations. Viewing a member ID card alone does not ensure member eligibility:**

- Hoosier Health Cards are issued by FSSA DFR.
- Hoosier Care Connect members receive member ID cards from their individuals Managed Care Entities (MCEs): Anthem or MHS
- Hoosier Healthwise members receive member ID cards from their individual MCEs: Anthem, CareSource, MHS, and MDwise.
- Package A (Medicaid) is not listed on the card and can only be determined via the Provider Healthcare Portal.

Other VFC Considerations

Patient Status	VFC Eligible	IIS Category
Has private health insurance plan with Medicaid as secondary insurance	Yes	Medicaid
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit **and** has Medicaid as secondary insurance	Yes	Medicaid
Has private health insurance that covers all vaccinations and is AI/AN	Yes	AI/AN; however, provider should select the eligibility category most cost-effective for patient
Has Medicaid and is AI/AN	Yes	Medicaid or AI/AN Provider should use Medicaid for the administration fee because this provides the least out-of-pocket expense for the family
Has insurance plan that does not cover all ACIP recommended vaccines	Yes	Underinsured Patient can only receive vaccines not covered by insurance plan
Has health insurance covering all vaccines, but has not yet the plan's deductible or paid for other services received at visit	No	Ineligible for VFC This applies even when the primary insurer would deny reimbursement for the cost of the vaccine and its administration because the plan's deductible has not been met.
Has health insurance covering all vaccines, but the plan has a fixed dollar limit or cap on amount it will cover	Depends	NO - Insured until the fixed dollar limit is met YES - Underinsured after the fixed dollar limit is reached

Vaccine Transport

Required Vaccine Transportation Procedures

- If your office is moving locations and transporting vaccines, you **must** contact your IDOH Regional Quality Assurance Specialist. Relocating without notification may jeopardize VFC program enrollment status.
- Only appropriate packing materials (see following page) may be used to safely transport and/or temporarily store vaccines
    - If an acceptable portable refrigerator or freezer unit is used, unit preparation, packing and transport must follow the unit's guidelines (i.e. AcuTemp Coolers or Fridge-Freeze units).
    - Temporary storage (i.e. during unit cleaning; offsite clinics) is possible only when acceptable portable refrigerator or freezer units are used.
- Digital data loggers with continuous monitoring and recording capabilities **must be used** for all temperature monitoring during transport.
- Vaccines must be attended at all times during transport and/or temporary storage, including temperature documentation on the VFC Vaccine Emergency Transport Log.
    - If temperatures are not monitored during transport/temporary storage, the vaccine will be deemed wasted because there is no proof that temperatures remained within acceptable ranges, regardless of duration.
    - The responsible party will be held accountable to replace all wasted VFC doses per IDOH's Restitution policy.

- Packed vaccine may never be placed in the trunk of a vehicle.
- The receiving facility must immediately unpack and appropriately store vaccines into acceptable VFC vaccine storage units that are monitored using a DDL or other continuous monitoring system for which a MIN/MAX can be recorded once daily and point-in-time temperature recordings can be documented twice daily.

Varicella-Containing Vaccines

The vaccine manufacturer does not recommend transporting varicella-containing vaccines (MMR/V,VAR). If these vaccines must be transported in an emergency:

- They should be packed and transported in a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C).
- **Dry ice is never allowed.**
- If a portable freezer unit is not available and the vaccines cannot be packed in a unit that maintains +5°F or colder:

- Varicella-containing vaccines may be transported and stored at refrigerator temperatures between 36°F and 46°F (2°C to 8°C).
- Refrigerated varicella-containing vaccines must be used within 72 hours.
- Remaining refrigerated varicella-containing vaccine must be discarded if it is not used within 72 hours. This is considered a temperature excursion and must be documented on the Vaccine Incident Response Worksheet and a Vaccine Return completed. Refreezing varicella-containing vaccines that are stored at refrigerated temperatures is **prohibited**.

Supplies for Transport

Keep a copy in your emergency transport container.

Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.

Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand (this normally takes less than 5 minutes.

Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.

Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/-0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

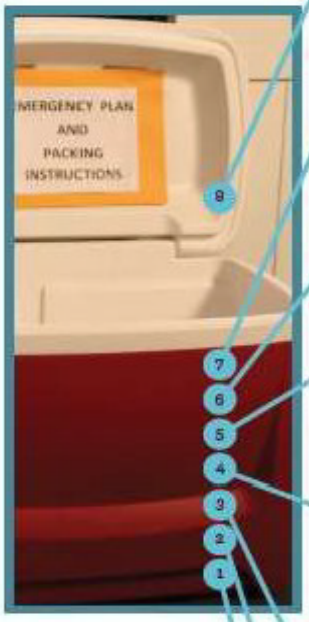
Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of Insulating cushioning material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**

Packing the Vaccine

Conditioning frozen water bottles (this normally takes less than 5 minutes)

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice "sticks," put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.




8. Temperature Monitoring Device Display (on lid)

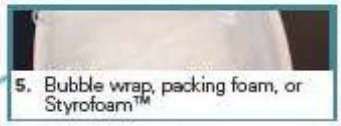
Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.


7. Conditioned Water Bottles

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.


6. Cardboard Sheet

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.


5. Bubble wrap, packing foam, or Styrofoam™

Insulating cushioning material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™


4. Vaccines, Diluents, and Temperature Monitoring Device Probe

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.
Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.
Vaccines – Stack boxes of vaccines and diluents on top of insulating material.


3. Bubble wrap, packing foam, or Styrofoam™

Insulating cushioning material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).


2. Cardboard Sheet

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.


1. Conditioned Water Bottles

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

NOTE:
This pack-out can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

Vaccine Transfer Procedures

Vaccine transfers involve the physical transfer of VFC vaccines and CHIRP inventory adjustments based on removal and receipt of VFC vaccines. Transfers are highly discouraged and should be rare events due to the possibilities of cold chain violations. Providers should use reminder recalls to avoid the transfer of vaccine whenever possible.

Transfers of private-purchased vaccines are up to the discretion of the owning facility and are not subject to approval or guidance from IDOH.

As a standard practice, opened vaccine boxes should not be transferred. Partially used multi-dose vials cannot be transferred. It is the discretion of the IDOH Staff Representative to allow transfers, based on need and cost efficiency.

Transfer of vaccines should only occur for the following reasons:

- Unopened vaccine is three months (90 days) or less from expiration date, AND provider will not be able to use inventory prior to expiration date.
- An area outbreak has resulted in unexpected surge of walk-in patients.
- VFC clinic closure/disenrollment requiring vaccine redistribution to other VFC providers.
- Clinics needing to offload and transfer vaccines due to seasonal closure (such as a school health clinic).

If your office is moving locations and transferring vaccine, you **must** contact your IDOH Staff Representative. **Relocating without notification may jeopardize VFC program enrollment status**.

All VFC providers **must** obtain prior approval before transferring any VFC vaccine to another VFC provider.*

- Contact your IDOH Staff Representative to issue a transfer request. Please allow up to 10 business days for transfer approvals. All vaccine transfers are at the discretion of IDOH staff.
- All VFC vaccine transfers **must** follow IDOH vaccine transport procedures, including reporting of the transfer in VOMS.

* Emergency vaccine transport to your backup storage facility is NOT considered a vaccine transfer and does not require advanced approval.

Offsite Clinics

Vaccine Transport, Use and Temperature Monitoring Procedures

Providers cannot transport vaccines to/from offsite clinics in hard-side coolers or coolers available at general merchandise stores. **All offsite clinics coordinated by VFC providers that plan on using VFC vaccine for patients must obtain approval from the IDOH at least two weeks prior to the event.**

Offsite Clinic Requirements:

- All clinics must use portable vaccine refrigerators/freezers or qualified pack-out units.
- Digital data loggers with a buffered probe and a current and valid Certificate of Calibration Testing must be placed directly with the vaccines and used to monitor vaccine temperature during transport.
- If vaccines are transferred to a permanent storage unit at the location of the offsite clinic, the storage unit must meet the minimum storage requirements for storage of VFC vaccines and the unit must have been monitored prior to the clinic day with a digital data logger.
- Vaccines must be monitored during the clinic using a digital data logger at least once an hour and documented on the Offsite Clinic VFC Vaccine Temperature Monitoring Log.
- Within the 24 hours following completion of the off-site clinic and return of all vaccines to the permanent storage unit, the data logger must be downloaded, and the report must be reviewed and sent to the respective Ordering and Accountability Specialist.

Use of Multi-dose Vials and Diluent at Offsite Clinics

- When a multi-dose vial is used, Food and Drug Administration (FDA) regulations require that it be used only by the provider's office where it was first opened. A partially used vial may be transported to or from off-site clinics operated by the same provider as long as the cold chain is properly maintained. However, such a vial may not be transferred to another provider or transported across state lines.
- Diluent should travel with its corresponding vaccine to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution.
- Diluent should be transported according to its manufacturer guidelines and should not come into direct contact with conditioned water bottles because of the potential for freezing.

Transport of Varicella-containing Vaccine to Offsite Clinics

- CDC strongly discourages transport of varicella-containing vaccines to off-site clinics, because varicella-containing vaccines (VAR, Varivax; MMRV, ProQuad; ZOS, Zostavax) are sensitive to temperature excursions.
- Providers who choose to transport these vaccines to an offsite clinic must follow the appropriate procedures:
    - Transport in a portable freezer unit that maintains temperatures between -58°F and +5°F (-50°C and -15°C)
    - The use of **dry ice is not allowed**, even for temporary storage.

    - Discard reconstituted vaccine if not used within 30 minutes.
- **Exception – Requires Approval**
    - Varicella-containing vaccines may be transported and stored at refrigerator temperatures at offsite clinics, between 36°F and 46°F (2°C to 8°C). This vaccine can be refrigerated for up to 72 continuous hours prior to reconstitution at the offsite clinic. IDOH must approve the number of anticipated doses for use.
    - Varicella-containing vaccine stored at refrigerator temperatures must be discarded if it is not used within 72 hours. This is considered a temperature excursion and must be documented on the Vaccine Incident Response Worksheet and a Vaccine Return form completed. Refreezing varicella-containing vaccines that are stored at refrigerated temperatures is prohibited.

IDOH Immunization Division Contact List

VFC Enrollment and Operations

Contact for: • General VFC Enrollment questions	Phone	(317) 416-5929
	Fax	(317) 232-1913
	Email	enrollments@health.in.gov
	Availability	Mon. – Fri. ,8 a.m. to 4 p.m. ET

VFC Quality Assurance

Contact for: • VFC vaccine storage and handling • Temperature excursions • VFC compliance questions • Training webinars • Report facility change • Update VFC contacts	Phone	(800) 701-0704
	Fax	(317) 233-3719
	Email	immunize@health.in.gov
	Availability	Mon. – Fri., 8 a.m. to 4 p.m. ET

Vaccine Ordering Management System (VOMS)

Contact for: • Vaccine ordering, inventory, reconciliation, return or supply issues • VOMS training • VOMS user permissions	Phone	(800) 701-0704
	Email	immunize@health.in.gov
	Availability	Mon. – Fri., 8 a.m. to 4 p.m. ET

CHIRP Help Desk

Contact for: • General CHIRP assistance • Register a facility • Add or remove users	Phone	(888) 227-4439
	Email	CHIRP@health.in.gov
	Availability	Mon. – Fri., 8:30 a.m. to 5 p.m. ET

Document Center

Documents and forms can be found at the IDOH website at: www.in.gov/health/immunization

Emergency Vaccine Management Action Plan

Use the following guidance for emergency situations such as power outages, natural disasters, equipment failure or any event that results in vaccine storage outside of recommended temperature range. This includes responding to temperature excursions identified during DDL report reviews and those caused by human error (i.e. unit unplugged, unit door left open). *Post this Emergency Management Plan on your vaccine storage units.*

Emergency Contacts

In an emergency, contact the following people in the order listed below.

Role/Responsibility	Name	Phone	Email

Additional Contacts

Service	Name	Phone	Email
IDOH Staff Representative			
IDOH Immunization Division		(800) 701-0704	immunize@health.in.gov
Utility Company			
Building Maintenance			
Building Alarm Company			
Refrigerator/Freezer Alarm Company			
Refrigerator/Freezer Repair			
Vaccine Transport Contact			

Back-up Power Sources and Alternative Locations

Does the clinic have a generator?	
If so, where is it located and how often does it receive testing/maintenance?	

If your clinic does not have a generator and/or your vaccine storage until fails, it may be necessary to transport vaccines to an alternate storage location within your facility or offsite (e.g., a local hospital or another VFC provider).

Identify alternate, offsite locations that have vaccine storage units and temperature monitoring devices that meet VFC program requirements.

Alternate Location	Address	Contact Name	Phone	Email

Location of emergency packing supplies

Before an Emergency Checklist

Proper preparation for emergency situations is essential for protecting the viability of vaccines. Use the following checklist to help ensure practices are ready for planned or unexpected situations that might impact vaccines.

Step	Description
1	Maintain current emergency contact information for key practice staff.
2	Maintain current contact information for alternate vaccine storage location(s), including the facility name, address, and telephone number.
3	Be familiar with backup power sources for your office (e.g. back-up generator).
4	Stock vaccine packing and transport supplies, including back-up digital data loggers.
5	Review (at least annually) the steps key practice staff must take to protect vaccines during all emergency situations, including how to pack and transport vaccines.

Scheduled Power Outage Checklist

Step	Description
1	Notify the emergency contacts listed in this emergency plan and the IDOH staff representative.
2	Contact an alternate storage facility to verify they can accept the vaccines and make a plan for transport. Update all contacts of proposed plan.
3	Pack and transport vaccine per IDOH procedures.
4	Once power has been restored, verify storage units are functioning properly and that temperatures have stabilized within acceptable temperature ranges.
5	Notify and update emergency contacts.
6	Follow the same vaccine transport procedures and return vaccine to its original storage unit.

During an Emergency Checklists

Follow the checklist that best applies to your emergency.

Power Outage/Natural Disaster

Step	Description
1	Keep calm and do not open the unit.
2	Place a "DO NOT OPEN" sign on vaccine storage unit(s) and leave door(s) shut to conserve cold air mass.
3	Notify the emergency contacts listed in this emergency plan.
4	Note the time the outage started and storage unit temperatures at the time of power loss; continue monitoring temperatures, even if they go out of range.
5	Assess the situation to determine the cause of the power failure and estimate the time it will take to restore power.
6	**If the outage is expected to last longer than two hours:** • Contact the alternate storage facility to verify they can accept the vaccines. • If vaccines will be relocated, refer to the Vaccine Transport section for instructions. • If transport or relocation is not feasible (e.g., alternate location not available or travel conditions are unsafe), keep vaccine storage units closed and notify the IDOH Staff Representative.
	If the outage is expected to last less than two hours: • Keep units closed and do not allow staff to use any vaccine. • Do not transport or discard vaccine.
7	Monitor vaccine storage unit temperatures until power is restored.
8	Once power has been restored, follow all steps listed in After an Emergency.

Human Error (Unit Unplugged/Unit Door Left Open)

Step	Description
1	Upon hearing the alarm, identify and rectify the issue immediately (i.e. plug the unit in, shut the door).
2	Keep calm and do not open the unit.
3	Place a "DO NOT OPEN" sign on vaccine storage unit(s) and leave door(s) shut.
4	Notify the emergency contacts listed in this emergency plan.
5	Note the time the alarm started and storage unit temperatures at the time of alarm.

6	Monitor the temperatures until they have stabilized to acceptable ranges.

7	**If vaccines were exposed to out-of-range temperatures:**
	• Label affected vaccines "Do Not Use" and keep them in the storage unit in acceptable temperatures. **Do not** remove them from the unit or discard the vaccine.
	• Document and report the excursion to your IDOH Staff Representative.
	• If vaccines are deemed spoiled by the manufacturer*:
	  ○ Adjust inventory and submit return in VOMS.
	  ○ Place a vaccine order in VOMS.
	  ○ Fill out the Temperature Excursion Reporting form and submit it to your Ordering and Accountability Specialist.
	* You must obtain a case number for your temperature excursion from the manufacturer. If the manufacturer is closed, keep the vaccines labeled "Do Not Use" until a case number is obtained.

8	Educate staff based on the identified human error issue (i.e. never unplug a vaccine storage unit).

Responding to an Identified Temperature Excursion from DDL Report Review

Step	Description
1	Keep calm and do not open the unit that was affected.
2	Place a "DO NOT OPEN" sign on vaccine storage unit(s) and leave door(s) shut to conserve cold air mass.
3	Notify the emergency contacts listed in this emergency plan.
4	Note the time the excursion started and ended as well as the minimum and maximum temperatures reached during the excursion event.
5	Complete the Temperature Excursion Reporting Form and send it to your Ordering and Accountability Specialist.
6	If the storage units were a contributing factor to the excursion and need to be repaired, **and** the vaccine is still viable: • Contact an alternate storage facility to verify they can accept the vaccines. • Refer to the Vaccine Transport section for instructions to safely relocate vaccines. • Follow the After an Emergency: Storage Unit Repair/Replacement plan.
	If the storage units were the contributing factor to the excursion and need to be repaired, **and** the vaccine is **not** viable: • If vaccines are deemed spoiled by the manufacturer*:

	○ Adjust inventory and submit return in VOMS. ○ Place a vaccine order in VOMS. ○ Fill out the Temperature Excursion Reporting form and submit it to your Ordering and Accountability Specialist. * You must obtain a case number for your temperature excursion from the manufacturer. If the manufacturer is closed, keep the vaccines labeled "Do Not Use" until a case number is obtained.

Vaccine cannot be stored in a combination unit when moving or changing units. Vaccine should be taken to a backup location and stored until five days of stable temperatures can be obtained.

After an Emergency Checklist

Step	Description
1	Verify storage units are functioning properly.
2	Note the time that power was restored and/or temperatures stabilized within range, and document the storage unit temperatures (CURRENT, MIN and MAX) at that time.
3	Once vaccine storage unit temperatures have stabilized, notify the emergency contacts.
4	**If vaccines were transported:** • Follow the same transportation procedures and transfer vaccine back to its original storage unit (Refer to the Vaccine Transport section for instructions).
	If vaccines were maintained at required temperatures: • Remove the "DO NOT OPEN" sign from storage unit(s). • Notify staff that vaccines may be used.
	If vaccines were exposed to out-of-range temperatures: • Label affected vaccines "Do Not Use" and keep them in the storage unit in acceptable temperatures. **Do not** remove them from the unit or discard the vaccine. • Document and report the excursion to your IDOH Staff Representative. • If vaccines are deemed spoiled by the manufacturer*: ○ Adjust inventory and submit return in VOMS. ○ Place a vaccine order in VOMS. ○ Fill out the Temperature Excursion Reporting form and submit it to your Ordering and Accountability Specialist. * You must obtain a case number for your temperature excursion from the manufacturer. If the manufacturer is closed, keep the vaccines labeled "Do Not Use" until a case number is obtained.

Storage Unit Repair/Replacement

Step	Description
1	Facilitate all storage unit repairs and or replacements. Involve your IDOH Staff Representative in any unit purchase to ensure it meets requirements.
2	Once repairs are completed, or a new unit is installed, verify the unit is functioning properly. Record date of repair and update/add any unit information on the Vaccine Storage Unit list contained within this plan.
3	Monitor unit temperatures using a DDL/continuous monitoring device and record all temperatures on the corresponding unit temperature log. Water bottles should be placed in the unit at this time. It may take 2 to 7 days to stabilize the temperature in a newly installed or repaired unit. **Do not move vaccines back to the unit until stable temperatures have been reached and approval received from your IDOH Staff Representative.**
4	Once you have obtained 5 days of temperature recordings, submit temperature logs to your IDOH Staff Representative for review. Await instruction for transport or to continue monitoring the unit.
5	When approval is received, follow the Vaccine Transport guidelines and return vaccine to its original (or replaced, if applicable) storage unit.
6	Continue daily routine temperature monitoring.

Vaccine Storage Troubleshooting Record

Refrigerator ☐ Freezer ☐

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges. Send this form to your IDOH Ordering and Accountability Specialist.

Date & Time of Event If multiple, related events occurred, see Description of Event below.	**Storage Unit Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
	Temp when discovered:		Temp when discovered:		
	Minimum temp:	Maximum temp:	Comment (optional):		

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event and last documented reading of storage temperature in acceptable range (2° to 8°C [36° to 46°F] for refrigerator; -50° to -15°C [-58° to 5°F] for freezer)
- Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after the manufacturers determine viability and you can obtain a case number).
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What steps did you take to prevent a similar issue from happening in the future?

Results

What happened to the vaccine? Did the manufacturers tell you to use or waste the vaccine? Please record the Case Number here.
Send this form to your Ordering and Accountability Specialist.

Case #:

Staff Acknowledgements

By signing below, I am indicating that I have read through this Vaccine Management Plan and fully understand this facility's responsibilities regarding publicly-funding vaccines.

Employee Name	Employee Signature	Title/Position	Date