

VACCINE MANAGEMENT PLAN

Routine Vaccine Operating Procedures and Emergency Storage & Handling

Medical Director:			
Primary Vaccine Coordinator:			
Back-up Vaccine Coordinator:			
Date Reviewed:		Reviewed By:	

VACCINE MANAGEMENT PLAN

The following document details up-to-date standard operating procedures for routine and emergency vaccine management. The plan addresses the following:

- Contact information for current primary and back-up vaccine coordinators
- Provider staff roles and responsibilities
- Documented training related to vaccine management
- Proper storage and handling practices, including how to handle a temperature excursion
- Procedures for vaccine ordering, receiving, inventory control, stock rotation, and handling vaccine loss and waste
- Procedures for emergency situations, including transport, equipment malfunction, power failure, and natural disaster

COORDINATORS AND CONTACTS

VACCINE MANAGEMENT STAFF

The following individuals have primary responsibility for maintaining all procedures related to proper vaccine storage and handling, inventory management, and training of office staff. An additional back-up is optional.

Vaccine Coordinator	Name	Phone	Email
Primary:			
Back-up:			
Back-up (optional):			

IMMUNIZATION RESOURCES

The following organizations and individuals are available for immunization questions and support.

Organization	Name/Title	Phone	Email
		208-334-5931	IIP@dhw.idaho.gov
Idaho Immunization Program	Quality Assurance Specialist		
Local Public Health District			

ADDITIONAL RESOURCES

Type	Name	Phone
Immunization Resources	IIP Provider Resource Binder	www.immunizeidaho.com
Power Company		
Refrigerator Repair		
Freezer Repair		
Alarm Company		
Emergency Vaccine Storage		

VACCINE COORDINATOR RESPONSIBILITIES

The primary vaccine coordinator is responsible for providing oversight for all vaccine management within the office and ensuring all vaccines are stored and handled correctly. In addition, the back-up vaccine coordinator must be appropriately trained, and ready to assume oversight in the absence of the primary vaccine coordinator.

The primary and back-up vaccine coordinator responsibilities include, but are not limited to, the following activities:

- Ordering vaccines
- Overseeing proper receipt and storage of vaccine deliveries
- Monitoring and documenting vaccine inventory and accountability information
- Organization of vaccines within storage units
- Setting up temperature monitoring devices
- Reading and recording minimum/maximum vaccine storage unit temperatures each morning during normal operating hours
- Responding to out-of-range temperatures (temperature excursion or incidents), which includes reporting all out-of-range vaccine storage temperatures to the IIP
- Downloading, reviewing, and submitting temperature data to the Idaho Immunization Program by email at IIP@dhw.idaho.gov, by the 7th of each month, for the previous month's temperatures (this bullet may be removed by PharmaWatch™ users who share access with IIP staff)
- Rotating vaccine stock at least weekly so vaccines with the earliest expiration dates are used first
- Notifying the IIP, in writing, within 90 days of any vaccine doses that will expire before they can be administered
- Removing expired vaccine from storage units immediately upon expiration
- Returning expired/spoiled vaccine to McKesson Specialty and accounting for all wasted/non-viable vaccines
- Maintaining all documentation and records pertaining to vaccines, such as inventory and temperature logs
- Ensuring all office staff are properly trained regarding their role with immunizations, including documentation
- Monitoring operation of storage equipment and temperature monitoring systems
- Overseeing proper vaccine transport (when necessary)
- Overseeing emergency preparations
 - Tracking inclement weather conditions
 - Ensuring appropriate handling of vaccines during a disaster or power outage
- Scheduling and participating in site visits

VACCINE STORAGE UNIT SPECIFICATIONS

Type of Unit (Refrigerator or Freezer)	Brand	Model	Serial Number	Location

MAINTENANCE PLAN

Vaccine storage units will be maintained by:

Name	Contact Information

Maintenance will be conducted on the following schedule:

Timeframe (quarterly, annual, etc.)	Month

Maintenance will include:

- Dust coils at the bottom or back of refrigerator and freezer (if applicable)
- Wipe the interior of the storage unit with warm, slightly soapy water and wipe dry to prevent the growth of mold, mildew, or fungus
- Visually inspect the seal around the door of the unit for any wear, brittleness, or cracks, at least once per month
- Vaccine staff should check that the doors of vaccine storage units are tightly shut daily

ALARM SYSTEM (optional)

The alarm system will be calibrated and maintained by:

Name	Contact Information

ROUTINE VACCINE STORAGE AND HANDLING REQUIREMENTS

The vaccine storage practices listed below are the responsibility of the primary vaccine coordinator and can be delegated to the back-up vaccine coordinator. If the practices are delegated, then the primary vaccine coordinator must monitor the activity.

- Store refrigerated vaccine at 36° to 46° F (2° to 8° C)
- Store frozen vaccine at -58° to +5° F (-50° to -15° C)
- Store vaccines requiring refrigeration in the middle of the refrigerator compartment away from the walls, floor, and cold air vent
- Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas
- Space stored vaccine to allow for cold air circulation around the vaccine
- Only vaccines are to be stored in the refrigerator and freezer
- Do not store vaccines in the door or in the drawers of the storage unit
- Remove vegetable bins from the refrigerator and replace with cold water bottles
- Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles
- Store vaccines in their original packaging, with the lids closed and in place, until ready to administer to protect them from sunlight and fluorescent light
- Store vaccine products that have similar packaging in different locations to avoid confusion and medication administration errors
- Store MMR vaccine in the freezer
- Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine weekly
 - Notify the IIP, in writing, within 3 months (90 days) of any vaccine doses that will expire before they can be administered. Only with the approval and direct guidance of the IIP, and only if the cold chain can be ensured, can short-dated vaccines be redistributed to providers who are able to administer them before the vaccines expire.
- Immediately remove expired vaccine from the storage unit
- Prepare vaccines immediately prior to administration; pre-drawing vaccine into syringes is not an acceptable practice
- “Do not unplug” stickers must clearly mark all electrical outlets and circuit breakers of every vaccine storage unit
- Vaccine storage units cannot be plugged into GFI outlets (with a reset button), outlets that can be activated by a wall switch, or multi-outlet power strips

If a provider has privately purchased vaccine, then the vaccine must be marked and/or separated from the vaccine supplied by the IIP. Suggestions to differentiate between private and public vaccines include:

- Utilize State-Supplied stickers (blue) provided by the IIP
- Place vaccine on separate, marked shelves
- Place vaccine in separate storage units

MONITORING STORAGE CONDITIONS

Providers must store vaccines at the appropriate temperatures. The temperature range for refrigerated vaccine is 36° to 46° F (2° to 8° C). Frozen vaccine must be kept between -58° to +5° F (-50° and -15° C). Failure to store vaccine at proper temperatures can seriously compromise or destroy vaccine efficacy.

- A certified and calibrated, continuous recording temperature device that meets IIP requirements is used to monitor temperatures. The devices used in this office are listed below:

Storage Unit	Device Type	Calibration Date

- A certified and calibrated, continuous recording temperature device that meets IIP requirements is available as a back-up to use to monitor temperatures. The device(s) used in this office is listed below:

Location	Back-up Device Type	Calibration Date

- A current certificate of calibration for each device is on file with the IIP and easily accessible in the office for review during site visits
- The current minimum and maximum refrigerator and freezer temperatures are checked and documented (time, date, name/initials, temperature) at least once daily at the start of each clinic day
- Temperature logs are maintained for at least three years
- Temperatures are downloaded, saved at the clinic, and submitted to the IIP monthly, or whenever temperatures are found to be out-of-range
 - The temperature files are saved: _____
(location of electronic files)
- All clinic staff are trained to take immediate action if storage unit temperatures are out of range or the thermometer is alarming

VACCINE ORDERING AND INVENTORY

VACCINE ORDERING

- _____ will be responsible for ordering vaccines and maintaining vaccine stock.
(Responsible Staff)
- Vaccines will be ordered according to actual vaccine need on the following ordering cycle:

Frequency (monthly, bimonthly, quarterly, etc.)	First or Second Half of Month

- Prior to ordering, an on-hand inventory count must be entered in Idaho’s Immunization Reminder Information System (IRIS) and submitted to the IIP.
- Order vaccine brands listed on the Vaccine Brand Choice Form submitted to the IIP.
 - The submitted Brand Choice Form can be found in IRIS.
- Order and stock enough vaccines to ensure adequate supply to meet the needs of the patients.
- Running a Doses Administered report in IRIS can show how many vaccines were administered between selected dates and can help determine vaccine ordering quantities.

VACCINE INVENTORY MANAGEMENT

- Vaccine inventory counts, or accountability, will be completed before ordering according to the following schedule (best practice is to complete and submit accountability monthly):
 - Submit the actual, physical on-hand counts of vaccine in the office even if it does not match the number of doses specified as on-hand in IRIS.

Frequency (monthly, bimonthly, quarterly, etc.)	First or Second Half of Month	Day of the Week

- Store and rotate vaccines according to expiration date and use vaccines with the shortest expiration dates first.
- Vaccine rotation is conducted on: _____ (day of the week)
- Vaccine may be borrowed between IIP participating providers when needed and will be accounted for in IRIS by completing a vaccine transfer. Vaccine will be packaged and transported according to standards listed under *Vaccine Transport*.
 - Vaccines may **not** be borrowed between IIP-supplied and privately purchased vaccines.
 - If vaccines are within 90 days of expiration and will not be used, then contact the IIP at IIP@dhw.idaho.gov with the vaccine type, brand, lot number, expiration date, and number of doses to see if another provider may be able to use the vaccines before expiration.

RECEIVING VACCINE

RECEIVING VACCINE

- Vaccine is received by: _____
(name of designee)
- If the above designee is unavailable, notify: _____
(name of alternate designee)

Upon receipt of a shipment containing DTaP, DT, Hepatitis B, Hepatitis A, HIB, HPV, Influenza, IPV, MCV, MenB, MMR, PCV, PPSV, Tdap, Td, or Rotavirus:

- Check the heat indicator and cold temperature monitors included in your vaccine shipment to ensure that the vaccine has been in an insulated container, on ice or cold packs, at a temperature of 36° to 46° F (2° to 8° C). This should be done within two hours of delivery.
 - If either monitor indicates vaccine temperatures have been out of range (warmer than 46° F or colder than 36° F), then immediately call McKesson Specialty at 1-877-836-7123 and then call the IIP at 208-334-5931.
- Compare the vaccine received with the packing list to ensure that vaccine type, lot number, expiration date, quantity, and NDC match.
 - If there are discrepancies, then contact the IIP at 208-334-5931.
- Place the vaccine in the refrigerator (keeping it separate from any privately purchased vaccine).
- Rotate the stock by placing the new vaccine in the back and pulling the older vaccine to the front.
- Store the **MMR** in the freezer with the Varicella and the MMRV.
- Check to make sure all the vaccine ordered through the IIP was received by comparing the packing slip with the original order placed in IRIS.
- Accept the vaccine transfers in IRIS by following these steps:
 - Log in to IRIS,
 - Under **Inventory** click *manage transfers*,
 - On the **manage transfers** screen under **Inbound Transfers** click the *create date* (in blue) of the order,
 - Verify the vaccine received and if correct, click the *Accept transfer* button, and
 - If there is a discrepancy between what was received and the inbound transfer in IRIS please contact the IIP at 208-334-5931 prior to accepting the transfer.
- Maintain vaccine packing slips for three years.
- Contact the IIP at 208-334-5931 with any discrepancy/damage within 2 hours of receiving the vaccine shipment.

Upon receipt of Varicella or MMRV:

- Varicella and MMRV vaccine should arrive frozen. The temperature should be between -58° and +5° F (-50° to -15° C)
- Determine the length of time the vaccine was in transit by looking at the packing list:
 - Varivax orders of 50 doses or more will be shipped in the large 4-day box (vaccine is viable for 4 days from shipping date). Varivax orders of 40 doses or fewer will be shipped in the small 2-day box (vaccine is viable for 2 days from shipping date), unless those 40 doses or fewer are shipped on a Thursday or Friday in the large 4-day box for delivery on Monday.
 - ProQuad orders are viable for 1 day regardless of shipping container size.

- If frozen vaccine was in transit longer than the shipping box indicates viability, then contact Merck at 1-800-637-2579 and then contact the IIP at 208-334-5931.
- Follow the check-in procedure as detailed above, except be sure to store Varicella-containing vaccines in the freezer.

EXPIRED, SPOILED, OR WASTED VACCINE

EXPIRED/WASTED VACCINE

- Expired/wasted vaccine is processed in IRIS by: _____
(name of designee)

- Immediately upon determining that a vaccine is expired or non-viable/spoiled, remove it from the storage unit, place it in a bag or box, and mark DO NOT USE. Notify designee listed above.
 - Expired or Spoiled Vaccine is nonviable vaccine in its original container (vial or syringe) that is returned to McKesson Specialty Distribution, LLC for federal excise tax credit. The expired or spoiled vaccine must be reported to the IIP and returned to McKesson **within six months of loss**. Returnable vaccine includes expired vaccine or vaccine that are non-viable because of the following:
 - Natural disaster / power outage
 - Refrigerator/freezer too warm or too cold
 - Failure to store properly upon receipt
 - Vaccine spoiled in transit
 - Mechanical failure (of vaccine storage unit)
 - Spoiled (vaccine in its original packaging that has been destroyed by another means not listed here)
 - Recall (vaccine that has been recalled)

- Immediately upon determining that a vaccine is wasted, notify designee, then dispose of according to business practices.
 - Wasted Vaccine is nonviable vaccine that cannot be returned for federal excise tax credit. Wasted vaccine must be reported to the IIP at least with each vaccine order and disposed of per the provider's business practices. Wasted vaccine includes the following:
 - Broken vial/syringe
 - Vaccine drawn up into syringe but not administered (including a needle being placed on a pre-filled syringe)
 - Lost or unaccounted-for vaccine
 - Non-vaccine products (e.g. IG, HBIG, diluent)
 - Open vial from which all the doses have not been administered

PROVIDER EDUCATION

ANNUAL TRAINING REQUIREMENT

The primary and back-up vaccine coordinator must complete and document annual training by completing one of the following:

- Participation in a VFC Compliance Site Visit with IIP staff, or
- Participation in an Educational Site Visit with health district staff, or
- Completion of two web-based training modules. CDC's *You Call the Shots: Vaccine Storage and Handling* and *Vaccines for Children (VFC)* located at <https://www.cdc.gov/vaccines/ed/youcalltheshots.html>.
 - After the training is complete, print the certificate of completion. Document the coordinator's name and the date of the training and keep a copy on file for review by the IIP.

EDUCATIONAL REQUIREMENTS

- The Vaccine Management Plan is posted on or near vaccine storage units and accessible to all staff.
- Every new staff member is trained on the topics covered in this plan at the time of orientation/hire.
- The Vaccine Management Plan is reviewed with all staff annually and the training documented.
- All immunization trainings are documented (see Attachment 1 – Immunization Training Log).
- All new staff are trained on vaccine use and handling, including preparation, protection from light, shelf life after reconstitution, checking labels and expiration dates before use, indications for use, and required documentation information for the patient record.
- Annual immunization-related training is documented for all staff who administer or manage immunizations. This includes attendance at the IIP conferences offered each spring and fall (Shot Smarts and Booster Shots), as well as other on-site trainings, web-based trainings, and distribution of written materials.
- Staff have immediate access to resources about vaccines, such as the CDC's *Epidemiology and Prevention of Vaccine-Preventable Diseases* (The Pink Book) and the CDC's *Vaccine Storage and Handling Toolkit* (<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>)
- Vaccine administration protocols, or standing orders, and recommended immunization schedules are posted near vaccine preparation areas.

VACCINE TRANSPORT

TRANSPORTING/PACKING VACCINES

It is critical that vaccine viability is protected by maintaining the cold chain at all times during any vaccine transport. Temperatures during transport must be recorded using an IIP-approved, certified/calibrated thermometer. See CDC’s Emergency Transport resource for more information:

<https://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf>

Packing Vaccine for Transport:

- Use properly insulated containers to transport vaccine. These containers should be validated to ensure they can maintain the vaccine at the correct temperatures. Shipping containers received from McKesson can be used. DO NOT use containers from Merck, as they are able to be returned to Merck for redistribution. Alternatively, hard-sided, plastic, insulated containers/coolers or Styrofoam coolers with at least 2-inch-thick walls may be used, as well as portable refrigerator/freezer units.
- Pack enough conditioned frozen water bottles to maintain the cold chain during the entire transport. Do not use loose or bagged ice. The number and placement of conditioned frozen water bottles in the container will depend on container type, size, length of transport, and outside temperature.
- Place an insulating barrier (packing foam or bubble wrap) between the conditioned frozen water bottles and the vaccines to prevent accidental freezing.
- Pack vaccines in their original packaging on top of the barrier. Do not remove vaccine vials or pre-filled syringes from boxes.
- Place the certified/calibrated thermometer with the vaccines, then add the top insulating barrier and additional conditioned frozen water bottles.
- The contents should be layered as follows, starting from the bottom:
 - Conditioned frozen water bottles, insulating material, vaccines, certified/calibrated temperature monitoring device, insulating material, conditioned frozen water bottles.

Document the transfer/shipment by creating a transfer in IRIS so the receiving clinic can accept the transfer. If vaccines are being temporarily stored at a back-up location, then no transfer is needed in IRIS.

When transporting from the office to an offsite clinic, temperatures must be reviewed and documented at least hourly until the vaccine is safely stored in an approved storage unit.

Packing Material	Location at our Facility	Ordering Info	Number

EMERGENCY VACCINE MANAGEMENT PLAN

EMERGENCY CONTACTS & LOCATIONS

This plan should be followed any time the usual vaccine storage unit is not maintaining proper temperatures, such as during a power outage, vaccine storage unit malfunction, or other emergency.

Notify those listed below in the event of a power/storage unit failure:

Position	Name	Phone Number
Primary Emergency Contact		
Secondary Emergency Contact		
Additional Emergency Contact		
Person with 24-Hour Access		
Person with 24-Hour Access		

How will the designated persons be contacted in a vaccine storage emergency during normal business hours? How will they be contacted outside of normal business hours?

If the failure has lasted more than 1-2 hours and/or temperatures are not staying within range (Refrigerator 36° to 46° F; Freezer -58° to 5° F), then prepare vaccine for transport to another location until power is restored, or the storage unit malfunction is corrected, and the storage unit is maintaining an acceptable temperature reading. The alternate location should have proper refrigerator and freezer units, temperature monitoring capabilities, and backup power. Vaccines may not be stored in a storage unit at a personal residence or in a dorm-style unit for any amount of time.

Alternate Unit/Location	Contact Person	Address & Telephone Number

Other Contact Information	Name	Phone Number
Refrigerator/Freezer Repair Company		
Power Company		
Vaccine Storage Unit Alarm Company (if applicable)		
Generator Repair Company (if applicable)		
National Weather Service		

VACCINE TRANSPORT SUPPLIES

Packing Material	Location at our Facility	Ordering Info	Number

EMERGENCY TRANSPORT PROCEDURES

See CDC's Emergency Transport resource for more information:

<https://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf>

- Do not open the storage units until all preparations for packing and moving the vaccine have been made.
 - Contact backup location to confirm transport
 - Locate and gather all necessary supplies
- Pack all vaccines for transport in an insulated container per the guidelines outlined in the Vaccine Transport section.
 - Varicella has stringent temperature requirements and must be packed separately in an insulated container filled with as many ice packs as possible. Varicella-containing vaccines should never be transported on dry ice.
 - Mark all vaccine "Do Not Use" until the viability of the vaccine is determined.
- During transport, an IIP-approved continuous recording temperature monitoring device must be kept with the vaccine to continually record temperatures.
- Vaccine should never be moved in the trunk of a vehicle to prevent exposure to extreme hot or cold temperatures.
- Note the time the vaccine was removed from the refrigerator/freezer and the temperature of the units when vaccine is removed. Also note when the vaccine is moved into the alternate storage units.
- Notify the IIP by submitting a *Vaccine Temperature Incident or Alarm Report*.
 - The report is accessed online through IRIS on the **related links** tab or with the following link: [Temperature Incident or Alarm Report](#)

