

VACCINE MANAGEMENT PLAN



Facility Name: _____ **PIN:** _____

Name & Title of Person Responsible for Plan Content: _____

Signature: _____ **Date:** _____

- Vaccine Management Plans must be reviewed and/or updated at least annually or as changes occur. All information must be up-to-date at all times; a review date is required with an accompanying signature of the person responsible for the plan's content.
- If only minor changes need made, write in the necessary changes to that area and date/sign below; a new plan does not need completed each time unless major changes occur. Each time content is updated a signature and date is required.

Date of Most Recent Review/Update*	Signature of Person Responsible for Plan Content

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VACCINE COORDINATORS AND KEY STAFF

Contact	Name/Title	Primary Phone Number <i>(cell or home)</i>	Alternate Phone Number <i>(cell or home)</i>	Email Address
Vaccine Coordinator (1)				
Vaccine Coordinator (2)				
Other Trained Staff				
Other Trained Staff				
Other Trained Staff				

VACCINE COORDINATOR RESPONSIBILITIES

- A. Our facility is required to have at least two Vaccine Coordinators who are responsible for management of the Public Vaccine Program(s) in our facility.
- B. Any changes in key staff must be reported to the Immunization Program as soon as the change becomes known in our office.

Vaccine Coordinator responsibilities include, but are not limited to:

- A. Ordering all ACIP recommended vaccines for the patient population served
- B. Overseeing proper receipt and storage of vaccines
- C. Organizing vaccines within the storage units
- D. Ensuring that vaccine storage unit temperatures are recorded from a calibrated data logger thermometer a minimum of twice each day except weekends and state holidays
- E. Ensuring that vaccine storage unit minimum/maximum temperatures are recorded from a calibrated data logger thermometer once per day, in the morning, except weekends and state holidays
- F. Downloading and reviewing data logger data weekly; preferably Monday morning
- G. Inspecting storage units daily to ensure vaccines are being stored properly
- H. Rotating vaccine stock based on expiration dates

- I. Monitoring expiration dates and ensuring that expired vaccine is promptly removed from the storage unit(s)
- J. Responding immediately to any temperature excursions as outlined in the Vaccine Storage and Handling – Vaccine Viability – C. section of this Plan
- K. Overseeing proper vaccine transport
- L. Maintaining all documentation related to the vaccine program, vaccine storage and handling, and staff training for a minimum of 3 years
- M. Maintaining records, including public vaccine program eligibility screening and documentation for a minimum of 3 years
- N. Maintaining storage equipment records, to include any maintenance work/repairs
- O. Ensuring that designated staff is adequately educated and trained and that the training is documented

EDUCATION AND TRAINING

- A. Both Vaccine Coordinators are required to be trained at least annually on Public Vaccine Program requirements including proper storage and handling of vaccines.
- B. All staff members who handle or administer vaccines, including recording temperatures of vaccine storage units, should also receive comprehensive training at least annually regarding proper vaccine storage and handling and vaccine administration.
- C. Training should occur annually and:
 - a. during new staff orientation,
 - b. when program recommendations and requirements are updated, and
 - c. when new vaccines are added to our facility's inventory.
- D. Competency checks should be in place to ensure staff members are skilled and proficient.
- E. Documentation of all training will be retained using the staff training log found in Appendix A or an equivalent process.
- F. _____ will ensure training is completed by all required staff and that the training has been documented.
- G. If training assistance and/or resources are needed, please contact the Immunization Program to schedule on-site or web-based training/education.

VACCINE STORAGE AND HANDLING

Refrigerator/Freezer Temperature Monitoring:

- A. Refrigerator and freezer temperatures must be reviewed and recorded twice daily. Minimum and maximum temperatures must also be recorded once daily, in the morning.

- B. All vaccine storage unit temperatures must be monitored using a calibrated data logger thermometer and recorded on the Monthly Temperature Log.
- C. The most current version of the Monthly Temperature Log can be found at: www.immunizewyoming.com → Vaccine Programs → Provider Portal → Forms and Reports.
- D. Data logger data will be downloaded and reviewed weekly, preferably Monday.
- E. _____ will record temperatures and immediately contact the Immunization Program at 307-777-7952 if any vaccine storage unit temperatures are out of range (including minimum and maximum temperatures).
- F. _____ will notify a Compliance Specialist if our facility relocates any storage unit either within the facility or to a new location, or if our office will be closed for any length of time.
- G. If our office moves to a new location, a Moving Notification Form will be completed and sent to an Immunization Program Compliance Specialist. The Moving Notification Form is located at: www.immunizewyoming.com → Vaccine Programs → Provider Portal → Forms and Reports.
- H. At least one backup calibrated data logger thermometer will be available at all times in the event vaccines need to be relocated or if a thermometer in a storage unit stops working.
- I. All thermometers used in any vaccine storage unit(s) must be calibrated to CDC standards and a current Certificate of Calibration will be kept until expiration.
- J. Thermometers must be re-calibrated or replaced 2 years from the “Date of Calibration” (Report or Issue Date) that is listed on the calibration certificate. The certificate will expire two years from the date of initial calibration and the thermometer(s) will need to be re-calibrated at that time even if there is an expiration or re-calibration date listed on the certificate with a different date.
- K. Our Certificates of Calibration are located _____.

Vaccine Viability:

- A. Refrigerators used to store vaccines must maintain temperatures between 2° C & 8° C. (1.9°C and below is too cold & 8.1°C and above is too warm)
- B. Freezers used to store vaccines must maintain temperatures between -15° C and -50° C. (-14.9°C and above is too warm)
- C. If a temperature is found that is below 2° C or above 8° C, for the refrigerator or above -15° C for the freezer, DO NOT administer the vaccines and immediately take the following actions:
 - a. Immediately store vaccines at proper temperatures.
 - i. If the storage unit temperature is currently in range, the vaccines can remain in the unit.

- ii. If the storage unit temperature is currently out of range, follow the facility's Emergency Plan for Vaccine Relocation to relocate the vaccines to the backup storage unit.
 - b. Quarantine all vaccines exposed to out of range temperature and mark as DO NOT USE.
 - c. Immediately call the Immunization Program at 307-777-7952 for further instruction.
 - d. Download and review the data logger data; do not print the data logger file. The file will need to be emailed to the Compliance Specialist the out of range temperature is reported to.
- D. Always document any action taken when responding to any storage and handling problem on the bottom of the Monthly Temperature Log.

Storage Unit Requirements:

- A. Stand-alone refrigerator and freezer units are preferred for storing vaccine. Use of dormitory style refrigerators is prohibited for storing vaccines under any circumstances.
- B. Vaccines will be placed in the center of the storage unit, and stored in their original packaging.
- C. Water bottles marked "Do Not Drink" will be placed in the door, on the floor, on the top shelf, and along the walls of the refrigerator.
- D. Frozen ice packs will be placed around all frozen vaccine in the freezer.
- E. Food and drinks will not be stored in the vaccine refrigerator or freezer.
- F. All drawers/bins will be removed from the storage unit. If the drawers/bins cannot be removed, they will not be used and will be marked "DO NOT OPEN" to avoid accidentally being left open causing the door of the unit to not close properly.
- G. Storage units will be plugged directly into a wall electrical outlet; storage units will not be plugged into a surge protector.
- H. DO NOT DISCONNECT signs will be placed by the electrical outlet of the storage unit(s) and on the circuit breaker, designating the circuit breaker number to the storage unit(s) as well as who to contact in an emergency situation.

Vaccine Emergency Plan:

- A. In the event of refrigerator/freezer malfunction, power failure, natural disaster, or any other emergency that might compromise appropriate vaccine storage conditions, vaccines may need to be transported to an alternate location.
- B. Written procedures for relocation of vaccines in case of emergency (Emergency Plan) will be posted on all vaccine storage units.
- C. All staff are required to understand the Emergency Plan for Vaccine Relocation and know where it is located.

- D. The Emergency Plan must be reviewed and/or updated at least annually or more frequently if changes occur and all information must be up-to-date at all times. A “review date” is required with an accompanying signature of the person responsible for the plans content.
- E. The Emergency Plan is located: _____.

STORAGE AND HANDLING ERRORS

Common Storage and Handling Errors to Avoid:

- A. Designating only one person, rather than at least two, to be responsible for storage and handling of vaccines.
- B. Storing vaccine in a manner that could jeopardize its quality.
- C. Storing food and drinks in the vaccine refrigerator/freezer.
- D. Inadvertently leaving the refrigerator or freezer door open or having inadequate seals.
- E. Storing vaccine in a dorm-style refrigerator for **ANY** length of time.
- F. Recording temperatures only once per day, or not recording any temperatures on a required day on the temperature log.
- G. Recording temperatures for only the refrigerator or freezer, rather than both.
- H. Recording temperatures from a non-calibrated thermometer.
- I. Documenting out-of-range temperatures on vaccine temperature logs without reporting them to the Immunization Program.
- J. Discarding temperature logs at the end of every month instead of keeping them for three years.
- K. Discarding multi-dose vials 30 days after they are opened.
- L. Not having emergency plans for a power outage or natural disaster.
- M. Not contacting the Immunization Program immediately to report any problem.

VACCINE STORAGE UNIT MAINTENANCE

- A. Regular maintenance is necessary to help ensure that vaccine refrigerators and freezers work properly.
- B. If a storage unit is not working properly, i.e.; unit remains too warm or too cold after the unit’s thermostat is adjusted, unit is making noises that are not normal or louder than normal, etc., call the refrigerator/freezer repair company listed on page 15 right away.
- C. On the _____ day of every month the storage units will be cleaned to include:
 - a. Clean the inside of the refrigerator and freezer by wiping the inside and shelves with disinfectant or antibacterial wipes.

- b. Check the door seals by examining them to make sure that they are not torn or brittle. There should be no gaps between the seals and the body of the unit, when the doors are closed.
 - c. Clean the coils by using a duster to remove any visible dust.
 - d. NOTE: Do not unplug the unit or remove vaccines from the unit during cleaning.
 - i. If the unit needs to be unplugged or moved for any reason, relocate the vaccines with the backup data logger thermometer to the backup unit **prior** to doing so.
- D. If frozen vaccines are stored in a manual defrost freezer it will be defrosted regularly and as needed to avoid having frost build up in the unit.
- a. During defrost, the vaccines will be moved to the backup storage unit until the unit has been completely defrosted and the unit's temperature is in acceptable range.

IMPORTANT CONTACTS

Resource	Contact Person Name/Title	Phone Number	Email Address and/or Website
Refrigerator Repair Company			
Freezer Repair Company			
Thermometer Company			
Power Company			
Temperature Alarm System Company <i>(if applicable)</i>			
Generator Company <i>(if applicable)</i>			
Other:			

VACCINE STORAGE UNIT SPECIFICATIONS

Type of Unit <i>(e.g. stand-alone freezer)</i>	Brand	Model Number	Serial Number	Date of Purchase/ Put in Use	Location at Facility

VACCINE ORDERING

- A. _____ and _____ will be responsible for ordering vaccines and maintaining appropriate vaccine stock.
- B. Vaccine will be ordered every month as needed between the 1st and 5th, (regardless of weekends/holidays), using the Vaccine Order Management System (VOMS).
- C. Vaccine inventory will be reconciled every month, prior to placing a vaccine order.
- D. Temperature logs will be submitted to the Immunization Program each month, between the 1st and 5th, by email: wdh-vfcreporting@wyo.gov or by fax: 307-777-2913.

VACCINE RECEIVING

- A. Vaccines are received by _____.
- B. Staff who signs for receipt of vaccine will immediately take vaccines to _____ for storage.
- C. _____ will cross-check the contents of the shipment with the packing slip to be sure they match, determine if the shipping time was less than 48 hours (no more than 4 days for varicella-containing vaccines), and call the Immunization Program, within 2 hours of receipt of shipment, if there are any problems with the vaccine shipment.
- D. _____ will then place vaccines in the proper storage unit making sure vaccines with shorter expiration dates are placed in front of vaccines with longer expiration dates.

- E. All vaccine-packing slips must be kept for 3 years.
- F. Minimum hours of operation: In order for vaccine shipments to be delivered, we must be on site with trained staff available to receive vaccine at least one day a week other than Monday, and for at least four consecutive hours during that day.

INVENTORY CONTROL

- A. _____ will be responsible for managing vaccine inventory.
- B. No more than a 3 month supply of vaccine will be kept at all times, unless otherwise arranged with the Immunization Program.
- C. Short-dated vaccines (vaccines closest to expiration) will be placed in front of longer dated vaccines and used first.
- D. If short-dated vaccines are discovered that are not able to be used prior to the expiration date, they must be reported to the Immunization Program using the Short-Dated Vaccine Transfer Request, located at: www.immunizewyoming.com → Vaccine Programs → Provider Portal → Forms and Reports.

VACCINE WASTE

- A. _____ will be responsible for handling expired/wasted vaccine.
- B. Immediately upon the Immunization Program finalizing a cold chain investigation where vaccine is deemed non-viable, remove it from the storage unit, place it in a bag or box marked DO NOT USE. Reconcile non-viable vaccine out of the WylR immediately.
- C. Expired vaccines must be removed from the unit and marked DO NOT USE as soon as they expire. Reconcile expired vaccine out of the WylR immediately.
- D. Expired/wasted vaccine that qualifies for return to the distributor must be reported using the Vaccine Return Form. This form is located at: www.immunizewyoming.com → Vaccine Programs → Provider Portal → Forms and Reports. Instructions are provided on the form.
- E. Non-returnable vaccine will be reconciled out of the WylR inventory and disposed of properly.
- F. All returnable vaccine must be returned in its original packaging, vial, or manufacturer pre-filled syringe.

TRANSPORTING VACCINES

Vaccine Transport (to off-site clinics or to another provider):

- A. All vaccine transfers must be pre-approved by the Immunization Program.
- B. CDC discourages regular transport of vaccines. Proper management of vaccine inventory plays a major role in preventing the need to transport vaccines.
- C. Shipping vaccines is strictly prohibited.
- D. It is critical that vaccine viability is protected by maintaining proper vaccine storage temperatures at all times during any vaccine transport.
- E. Use properly insulated containers to transport vaccine. These containers should be validated to ensure they are capable of maintaining the vaccine at the correct temperatures. 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.
- F. Temperatures must be monitored using a calibrated data logger thermometer with a valid calibration when transporting vaccines.
- G. Pack enough refrigerated/frozen packs to maintain the cold chain. Do not use loose, bagged, or dry ice. The number and placement of refrigerated/frozen packs inside the container will depend on container type, size, and outside temperature.
- H. Place an insulating barrier (e.g., bubble wrap, crumpled brown packing paper, Styrofoam peanuts, or exam table paper) between the refrigerated/frozen packs and the vaccines to prevent accidental freezing.
- I. The contents of the container should be layered as follows, starting from the bottom:
 - a. refrigerated/frozen packs
 - b. barrier
 - c. vaccine
 - d. calibrated data logger thermometer
 - e. barrier
 - f. refrigerated/frozen packs
- J. Pack vaccines in their original packaging on top of the barrier. Do not remove vaccine vials from boxes or pre-fill syringes in advance.
- K. When transporting vaccine from the office, to an off-site clinic, temperatures must be monitored using a calibrated data logger thermometer. These data logger files must be emailed to the Immunization Program with the monthly temperature logs at the end of the month. Any out of range temperatures must be reported to the Immunization Program immediately.

VACCINE TRANSPORT SUPPLIES

Coolers/Packing Materials	Location at Our Facility	Ordering Information (Company)	Phone Number
Portable refrigerator/freezer units			
Insulated Coolers/Containers			
Insulating Barrier <i>(bubble wrap, Styrofoam peanuts, exam table paper, etc.)</i>			
Cold Packs			
Freezer Packs			
Calibrated Data Logger Thermometer(s)			
Flashlights			
Plastic Storage Bags (baggies)			
Plastic Storage Containers			
Sharpies			

ADMINISTERING VACCINES

Lyophilized (Freeze-Dried) Vaccines:

- A. A lyophilized vaccine may be a powder or a pellet that must be reconstituted with a diluent prior to administration. After a vaccine is reconstituted its shelf life varies by product. Refer to the FDA's package inserts found at www.immunize.org.
- B. Diluents vary in volume and type. They are designed to meet the volume, pH, and chemical needs of each vaccine.
- C. Diluents are NOT interchangeable unless specified by the manufacturer.
- D. Use only the specific diluent provided by the manufacturer of the vaccine you are reconstituting.
- E. Reconstitute vaccine immediately prior to administration.
- F. Check expiration dates on both the vaccine and the diluent.

- G. After reconstitution, observe the vaccine for color and appearance. If the vaccine cannot be suspended or does not look as described in the product information, label the vial DO NOT USE, and store it under appropriate conditions separate from other vaccines. Immediately call the Immunization Program for further guidance.
- H. Administer the vaccine soon after reconstitution to minimize the risk of reduced potency.

Single-Dose and Multi-dose Vaccine Vials:

- A. Do not open a single-dose vial until you are ready to use it.
- B. Once the cap is removed from a single-dose vial, it should be used by the end of the clinic day.
- C. Always check the vial to make certain that the correct vaccine has been selected before removing the protective cap.
- D. Remove the cap and draw up the vaccine immediately before administration.
- E. DO NOT predraw vaccines before they are needed.
- F. Multi-dose vials contain preservatives that prevent bacterial growth. Once opened they can be used through their expiration date, unless the product information specifies a time frame for use after opening that is different from the expiration date on the label.
- G. Mark each multi-dose vial with the date it was first opened (when the protective cap was removed).
- H. Whenever possible use all vaccine in one multi-dose vial before opening another.
- I. DO NOT use partial doses from two or more multi-dose vials to obtain a full dose of vaccine.

Predrawing Vaccines (Immunization Clinics):

- A. Predrawing vaccines is generally discouraged, however, a **limited amount** of vaccine doses may be predrawn in a mass immunization setting **IF** the following procedures are followed:
 - a. Only one type of vaccine should be administered at the clinic.
 - b. Vaccines should not be drawn up in advance of arriving at the clinic site.
 - c. At the clinic site, health care personnel may each draw up a small number of vaccine doses---no more than one multi-dose vial or 10 doses.
 - d. Patient flow should be closely monitored to avoid drawing up unnecessary doses.
 - e. At the end of the clinic day, any remaining pre-drawn vaccine doses should be discarded and removed from the WylR Inventory as Wasted/Predrawn.
 - f. Vaccine doses that have been drawn up and not administered should NOT be used on subsequent days.

IMMUNIZATION PROGRAM CONTACTS

Area	Contact Person Name/Title	Phone Number	Email Address
Storage & Handling, Site Visits	Kristy Westfall Compliance Specialist	307-777-6519	kristy.westfall1@wyo.gov
	LaChel May Compliance Specialist	307-777-5960	lachel.may@wyo.gov
Program Requirements, Vaccine Ordering, WylR Inventory	Jude Alden, MBA VFC Coordinator	307-777-2413	jude.alden@wyo.gov
	Lisa Sara Provider Support Specialist	307-777-8503	lisa.sara@wyo.gov
Clinical Services	Val Knepp, RN Clinical & AFIX Specialist	307-777-8981	val.knepp@wyo.gov
Wyoming Immunization Registry (WylR)	John Anderson, M.A. WylR Coordinator	307-777-5773	john.anderson@wyo.gov
	Allison Buck, MPH WylR Support Specialist	307-777-7481	allison.buck@wyo.gov

Additional Information:

