Vaccine Management Plan

Facility Name: _____

Initial Implementation Date: _____

Name & Title of Person Responsible for Plan Content: _____

Signature: _____

Date Reviewed/Updated*	Signature of Person Responsible for Plan Content

**Vaccine Management Plans 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.*

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Vaccine Coordinator Responsibilities

Responsibilities include, but are not limited to:

- Ordering ACIP recommended vaccines
- Overseeing proper receipt and storage of vaccines
- Organizing vaccines within the storage units
- Ensuring that vaccine storage unit temperatures are recorded from a calibrated thermometer a minimum of twice each day except weekends and state holidays
- 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
- Downloading and reviewing data logger data weekly; preferably Monday morning
- Inspecting storage units daily
- Rotating vaccine stock
- Monitoring expiration dates and ensuring that expired vaccine is promptly removed from the storage unit(s)
- Responding immediately to any temperature excursions
- Overseeing proper vaccine transport
- Maintaining all documentation regarding vaccine storage and handling and staff training for a minimum of 3 years
- Maintaining records, including VFC/WyVIP program eligibility screening and documentation for a minimum of 3 years
- Maintaining storage equipment records, to include any maintenance work/repairs
- Ensuring that designated staff is adequately educated and trained and training is documented
- Reporting any changes in key staff to the Immunization Program as soon as the change is known

Vaccine Coordinators & Key Staff

Contact	Name/Title	Primary Phone Number (cell or home)	Alternate Phone Number (cell or home)	E-Mail Address
Primary Vaccine Coordinator*				
Secondary Vaccine Coordinator*				
Other Trained Staff				
Other Trained Staff				
Other Trained Staff				

**Our facility is required to have at least two Vaccine Coordinators who are responsible for management of the VFC/WyVIP Program in our facility.*
**Any changes in key staff will be reported to the Immunization Program as soon as the change becomes known in our office.*

Immunization Program Contacts

Area	Contact Person Name/Title	Phone Number	E-Mail Address
Storage & Handling, Site Visits	**Kristy Westfall** Compliance Specialist	307-777-6519	kristy.westfall1@wyo.gov
Program Requirements, Vaccine Ordering, WyIR Inventory	**Jude Alden, MBA** Vaccine Coordinator **LaChel May** Provider Support Specialist	307-777-2413 307-777-8503	jude.alden@wyo.gov lachel.may@wyo.gov
Clinical Services	**Val Knepp, RN** Clinical & AFIX Specialist	307-777-8981	val.knepp@wyo.gov
Wyoming Immunization Registry (WyIR)	**John Anderson, M.A.** WyIR Project Coordinator	307-777-5773	john.anderson@wyo.gov

Education and Training

A. Both Vaccine Coordinators are required to be trained on VFC Program Requirements including proper storage and handling of vaccines at least annually.

B. All staff members who handle or administer vaccines, including recording temperatures of vaccine storage units, should also receive comprehensive training regarding proper vaccine storage and handling and vaccine administration at least annually.

C. Training should occur during new staff orientation and/or when recommendations are updated or new vaccines are added to our facility's inventory. Competency checks should be in place to ensure staff members are skilled and proficient.

D. Documentation of all training will be retained using a staff training log or equivalent process.

E. A Staff Training Log template is located in Appendix A.

F. Staff training will be conducted at least _____.

G. _____ will ensure training is completed by all required staff and that the training has been documented.

H. If training assistance and/or resources are needed, please contact the Immunization Program to schedule on-site or web-based training/education.

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 (72 hours for varicella-containing vaccines), will call the Immunization Program, within 2 hours, if there are any problems with the shipment.

D. _____ will then place vaccines in the proper storage unit.

E. All vaccine-packing slips must be kept for 3 years.

F. Minimum hours of operation: In order for shippers to be able to deliver vaccine, we must be on site with appropriate staff available to receive vaccine at least one day a week other than Monday, and for at least four consecutive hours during that day.

Vaccine Storage and Handling

A. <u>Refrigerator/freezer temperature monitoring:</u>

1. Refrigerator and freezer temperatures are to be read and recorded from a calibrated thermometer on the VFC/WyVIP monthly temperature log twice daily. Minimum and maximum temperatures are to be read and recorded from a calibrated data logger only, once daily in the morning, on the VFC/WyVIP monthly temperature log.
2. The most current version of the VFC/WyVIP monthly temperature log can be found on the VFC/WYVIP Program webpage under Forms and Reports at www.immunizewyoming.com.
3. Data logger data will be downloaded and reviewed weekly, preferably Monday.
4. _____ will record temperatures and immediately contact a Clinical & Quality Compliance Specialist if any vaccine storage unit temperatures are out of range (including minimum and maximum temperatures).
5. _____ will notify a Compliance Specialist if our relocates any storage unit, or if our office will be closed for any length of time.

6. If our office moves to a new location, a Moving Notification Form will be completed and sent to the Immunization Program Compliance Specialist. The Moving Notification Form is located on the VFC/WYVIP Program webpage under Forms and Reports at www.immunizewyoming.com.
7. All thermometers used in any storage unit(s) must be calibrated to CDC standards and a current Certificate of Calibration will be kept until expiration.
8. At least one backup calibrated 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.
9. Certificates of Calibration that do not have an expiration or re-calibration date (or if the re-calibration date is more than two years from the initial calibration date) will expire two years from the date of initial calibration and the thermometer(s) will need to be re-calibrated at that time.
10. Our Certificates of Calibration are located _____.

B. Vaccine Viability:

1. 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 hot)
2. Freezers used to store vaccines must maintain temperatures between -15° C and -50° C. (-14.9°C and above is too hot)
3. 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 take the following actions:
   i. Place vaccines in a bag or box and mark DO NOT USE.
   ii. Continue to store vaccines at proper temperatures.
   iii. Immediately call the Immunization Program Clinical Specialist, _____for further instruction.
4. Always document any action taken when responding to any storage and handling problem on the bottom of the VFC/WyVIP monthly temperature log.

C. Storage unit requirements:

1. Stand-alone refrigerator and freezer units are preferred for storing vaccine. Use of dormitory style refrigerators is prohibited for storing vaccines under any circumstances.
2. Vaccines will be placed in the center of the storage unit, and stored in their original packaging.
3. 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.
4. Frozen ice packs will be placed around all frozen vaccine in the freezer.
5. Food will not be stored in the vaccine refrigerator or freezer.

6. All drawers/bins will be removed from the storage unit.
7. Storage units will be plugged directly into a wall electrical outlet; storage units will not be plugged into a surge protector.
8. 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).

D. Emergency Plan:

1. In the event of refrigerator/freezer malfunctions, power failures, natural disasters, or any other emergency that might compromise appropriate vaccine storage conditions, vaccines may need to be transported to an alternate location.
2. Written procedures for relocation of vaccines in case of emergency (Emergency Plan) will be posted on all vaccine storage units.
3. All staff are required to know the Emergency Plan.
4. 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.
5. The Emergency Plan can be located on/in: _____.

Vaccine Ordering

A. _____ and _____ will be responsible for ordering vaccines and maintaining 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: lachel.may@wyo.gov or by fax: 307-777-3615.

Inventory Control

A. _____ will be responsible for managing vaccine inventory.

B. A 2.5-3 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 be 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 on the VFC/WYVIP Program webpage under Forms and Reports at www.immunizewyoming.com.

Vaccine Waste

A. _____ will be responsible for handling expired/wasted vaccine.

B. Immediately upon the Clinical Specialist determining that vaccine is non-viable, remove it from the storage unit, place it in a bag or box marked DO NOT USE. Expired vaccines should also be removed and marked DO NOT USE.

C. Expired/wasted vaccine that qualifies for return to the distributor is reported using the Vaccine Return Form. This form is located on the VFC/WYVIP Program webpage under Forms and Reports at www.immunizewyoming.com.

D. Non-returnable vaccine will be reconciled out of the WyIR inventory and disposed of properly.

E. All returnable vaccine must be returned in its original packaging, vial, or manufacturer pre-filled syringe.

F. Expired vaccine must be returned no more than 3 months after expiration.

G. After the Vaccine Return Form has been submitted, an **Approved** Vaccine Return Form, that includes a **Vaccine Return ID**, will be faxed to our office within 10 business days.

H. When the **Approved** Vaccine Return Form is received, place the form into a shipping container, with the expired/wasted vaccine. Vaccines that are **not** on the approved form should **not** be included in the shipping container.

I. A shipping label that is directly tied to the Approved Vaccine Return Form will be sent to our office.

J. McKesson will notify UPS or FedEx to pick up the shipping container at our office.

Transporting Vaccines

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

1. All vaccine transfers must be pre-approved by the Immunization Program.
2. CDC discourages regular transport of vaccines. Proper management of vaccine inventory plays a major role in preventing the need to transport vaccines.
3. Shipping vaccines is strictly prohibited.
4. It is critical that vaccine viability is protected by maintaining the cold chain at all times during any vaccine transport.
5. 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.
6. Temperatures must be monitored using a data logger thermometer with a valid calibration when transporting vaccines.
7. Pack enough refrigerated/frozen packs to maintain the cold chain. Do not use loose or bagged ice. The number and placement of refrigerated/frozen packs inside the container will depend on container type, size and outside temperature.
8. 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.
9. The contents of the container should be layered as follows, starting from the bottom:
    i. refrigerated/frozen packs
    ii. barrier
    iii. vaccine
    iv. certified, calibrated thermometer
    v. barrier
    vi. refrigerated/frozen packs
10. Pack vaccines in their original packaging on top of the barrier. Do not remove vaccine vials from boxes or pre-fill syringes in advance.
11. When transporting vaccine from the office, to an off-site clinic, temperatures must be reviewed and documented **hourly** until the vaccine is safely stored in an approved storage unit. These temperature logs must be faxed to the Immunization Program with monthly temperature logs. Any out of range temperatures must be reported to the Clinical Specialist immediately.

Vaccine Transport Supplies

Coolers/Packing Materials	Location at Our Facility	Ordering Information (Company)	Phone Number
Portable refrigerator/ freezer units			
Insulated Coolers/ Containers			
Fillers (e.g., bubble wrap, Styrofoam, newspaper, exam table paper, etc.)			
Cold Packs			
Freezer Packs			
Calibrated Thermometers			
Flashlights			
Plastic Storage Bags (baggies)			
Plastic Storage Containers			
Sharpies			

Administering Vaccines

A. Lyophilized (Freeze-Dried) Vaccines:

1. 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.
2. Diluents vary in volume and type. They are designed to meet the volume, pH, and chemical needs of each vaccine.
3. Diluents are NOT interchangeable unless specified by the manufacturer.
4. Use only the specific diluent provided by the manufacturer of the vaccine you are reconstituting.
5. Reconstitute vaccine immediately prior to administration.
6. Check expiration dates on both the vaccine and the diluent.
7. 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 WDH Immunization Program for further guidance.
8. Administer the vaccine soon after reconstitution to minimize the risk of reduced potency.
9. Once a vaccine is reconstituted, its shelf life is limited and varies by product. Refer to the 2012 Vaccine Storage and Handling Guide for details.

B. Single-Dose and Multidose Vaccine Vials:

1. Do not open a single-dose vial until you are ready to use it.
2. Once the cap is removed from a single-dose vial, it should be used by the end of the clinic day.
3. Always check the vial to make certain that the correct vaccine has been selected before removing the protective cap.
4. Remove the cap and draw up the vaccine immediately before administration.
5. DO NOT predraw vaccines before they are needed.
6. Multidose 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.
7. Mark each multidose vial with the date it was first opened (when the protective cap was removed).
8. Whenever possible use all vaccine in one multidose vial before opening another.

9. DO NOT use partial doses from two or more multidose vials to obtain a full dose of vaccine.

C. Predrawing Vaccines (Influenza Clinics):

1. 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:
   i. Only one type of vaccine should be administered at the clinic.
   ii. Vaccines should not be drawn up in advance of arriving at the clinic site.
   iii. 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.
   iv. Patient flow should be closely monitored to avoid drawing up unnecessary doses.
   v. At the end of the clinic day, any remaining pre-drawn vaccine doses should be discarded and removed from the WyIR Inventory as Wasted/Pre-drawn.
   vi. Vaccine doses that have been drawn up and not administered should NOT be used on subsequent days.

Storage and Handling Errors

A. Common Storage and Handling Errors to Avoid:

1. Designating only one person, rather than at least two, to be responsible for storage and handling of vaccines.
2. Storing vaccine in a manner that could jeopardize its quality.
3. Storing food and drinks in the vaccine refrigerator/freezer.
4. Inadvertently leaving the refrigerator or freezer door open or having inadequate seals.
5. Storing vaccine in a dorm-style refrigerator for **ANY** length of time.
6. Recording temperatures only once per day, or not recording days on the temperature log.
7. Recording temperatures for only the refrigerator or freezer, rather than both.
8. Recording temperatures from a non-calibrated thermometer.
9. Documenting out-of-range temperatures on vaccine temperature logs without reporting them to the Immunization Program.
10. Discarding temperature logs at the end of every month.
11. Discarding multidose vials 30 days after they are opened.
12. Not having emergency plans for a power outage or natural disaster.
13. Not contacting the Immunization Program immediately to report any problem.

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.; too warm, too cold, too noisy, call the refrigerator/freezer repair company listed on page 15.

C. On the _____ day of every month the storage units will be cleaned to include:

- Clean the inside of the refrigerator and freezer by wiping the inside and shelves with disinfectant or antibacterial wipes.
- Vaccines may be moved around inside of the unit while cleaning and then moved back to their original location when finished.
- 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.
- Clean the coils by using a duster to remove any visible dust.
- NOTE: Do not unplug the unit or remove vaccines from the unit during cleaning.

Vaccine Storage Unit Specifications

Type of Unit	Brand	Model Number	Serial Number	Year of Unit	Date of Purchase/ Put in Use	Location at Our Facility

Important Contacts

Resource	Contact Person Name/Title	Phone Number	E-Mail Address
Generator Company (if applicable)			
Refrigerator Repair Company			
Freezer Repair Company			
Temperature Alarm System Company			
Thermometer Company			
Power Company			
Other			

Staff Training Log

This log sheet can be used to track required annual training for Vaccine Coordinators and other key staff.*

Facility Name: _____ PIN:_____

Name of Person who Completed the Training	Date of Training	Name/Type of Training (e.g. 2014 VFC/WyVIP Regional Training, Training w/ Immunization Program Staff, Training w/ other staff member(s) within our facility, webinar, CDC training, EZIZ training, etc.)	Name of Person or Organization that conducted the training

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