

Practice Name: \_\_\_\_\_

VFC PIN #: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_



## VACCINE MANAGEMENT PLAN

The Alabama Vaccines for Children (VFC) Program of the Alabama Department of Public Health (ADPH) - Immunization Division, in accordance with CDC guidelines, requires VFC providers to develop and maintain a vaccine management plan. This plan consists of clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs) for routine and emergency situations to protect vaccines and minimize loss due to negligence. The provider's vaccine management staff, consisting of a primary vaccine coordinator and backup vaccine coordinator, is responsible for implementing the plan. Provider office personnel and those working with vaccines should also be familiar with VFC requirements and the contents of this plan.

### Plan Requirements:

- Actions staff should take in the event of an emergency that might affect vaccine viability (e.g., unit malfunction, mechanical failure, power outage, natural disaster, or human error) that ensure all content, including emergency contact information and alternate vaccine storage location, is up to date.
- Primary Vaccine Coordinator and Backup Vaccine Coordinator must acknowledge review of the plan annually, as well as any staff assigned vaccine management responsibilities, by signing the signature page at the end of this document **annually**.
  - Primary Vaccine Coordinator (person **onsite** whose primary responsibility is to oversee VFC vaccine)
  - Backup Vaccine Coordinator (person **onsite** who will back up the Primary Vaccine Coordinator and oversee VFC vaccine in their absence)
- Annual review date and signature are both required by the individual responsible for content in order to validate the plan is current. When changes/updates occur to the plan, the individual responsible for updating content should sign and date the signature log at that time.
- Completed plan should be kept in a location easily accessible to staff, posted near vaccine storage units in case of an emergency, and available for review by ADPH immunization local field staff [Immunization Compliance Team Member/Immunization Compliance Manager (ICM)] during scheduled VFC compliance or drop in site visits.

For additional information/resources, refer to the Alabama VFC Program web site:

[www.alabamapublichealth.gov/immunization/vaccines-for-children.html](http://www.alabamapublichealth.gov/immunization/vaccines-for-children.html)

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## B. CURRENT PRIMARY VACCINE COORDINATOR AND BACKUP VACCINE COORDINATOR

Vaccine Management Staff			
Name	Title (e.g., MA, RN, LPN)	Office/Cell Phone	Email
Primary Vaccine Coordinator:			
Backup Coordinator:			

Designate primary vaccine coordinator and backup vaccine coordinator to be responsible for managing vaccine, as described in this plan. Backup coordinator will assume the responsibility of primary vaccine coordinator during the primary vaccine coordinator's absence. Therefore, both should be knowledgeable about vaccine management, and backup coordinator should be capable of fulfilling all vaccine storage and handling requirements.

NOTE: When Primary Vaccine Coordinator or Backup changes/is replaced (and training may be needed), you are required to notify your local Immunization Compliance Team Member. Refer to Immunization Field Staff Map: <https://www.alabamapublichealth.gov/immunization/assets/immunizationstaffmap.pdf> or call the Alabama VFC Program/ADPH - Immunization Division at #800-469-4599, or email: [vfc@adph.state.al.us](mailto:vfc@adph.state.al.us).

Primary Vaccine Coordinator responsibilities should include:

- Ordering vaccines
- Overseeing proper receipt and storage of vaccine deliveries
- Documenting vaccine inventory information
- Organizing vaccines within storage units
- Setting up temperature monitoring devices
- Checking and recording minimum/maximum temperatures at start of each workday
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends
- Rotating stock at least weekly so vaccines with the earliest expiration dates are used first
- Removing expired vaccine from storage units
- Responding to temperature excursions (out-of-range temperatures)
- Maintaining all documentation, such as inventory and temperature logs
- Organizing vaccine-related training and ensuring staff completion of training
- Monitoring operation of vaccine storage equipment and systems
- Overseeing proper vaccine transport (when necessary) per SOPs
- Overseeing emergency preparations per SOPs including tracking inclement weather conditions and ensuring appropriate handling of vaccines during a disaster or power outage

Primary vaccine coordinator responsibilities are to be completed by coordinator or delegated to appropriate staff. If delegated, coordinator should ensure designated staff is adequately trained. All staff members who receive vaccine deliveries, handle or administer vaccines, should be knowledgeable regarding requirements for temperature monitoring and storage equipment and be trained in vaccine-related practices and procedures.

Role of Vaccine Coordinator:

[www.alabamapublichealth.gov/immunization/assets/role\\_of\\_vaccine\\_coordinator.pdf](https://www.alabamapublichealth.gov/immunization/assets/role_of_vaccine_coordinator.pdf)

## C. PROPER VACCINE STORAGE AND HANDLING PRACTICES

### Alabama VFC Program Policies

- Vaccine Replacement
- Fraud, Abuse, and Wastage
- Borrowing

See: [www.alabamapublichealth.gov/immunization/vaccines-for-children.html](http://www.alabamapublichealth.gov/immunization/vaccines-for-children.html)

### Best Practices Resources

CDC Vaccine Storage and Handling Toolkit (updated March 2024):

[www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)

Immunization Action Coalition Clinic Tools Storage and Handling:

[www.immunize.org/clinic/storage-handling.asp](http://www.immunize.org/clinic/storage-handling.asp)

Proper vaccine storage and handling practices play a very important role in protecting individuals and communities from vaccine-preventable diseases (VPDs) so providers enrolled in the VFC program entrusted with publicly funded vaccine must ensure viability. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease, therefore, vaccine quality is the shared responsibility of everyone, from the time vaccine is manufactured until it is administered. Proper storage and handling begins with an effective vaccine cold chain, a temperature-controlled supply chain, which includes all vaccine-related equipment and procedures and relies on three main elements:

- 1) well-trained staff
- 2) reliable storage and temperature monitoring equipment
- 3) accurate vaccine inventory management

### Vaccine Storage - Selecting Storage Units (Refrigerators and Freezers)

Refrigerators and freezers are available in different types (stand-alone and combination) and grades (pharmaceutical, commercial, and household). CDC recommends the following vaccine storage unit types (in order of preference):

- Pharmaceutical-grade stand-alone or combination units (preferred);
- Household/commercial stand-alone units;
- Household/commercial combination units using the refrigerator section only

Types/grades of vaccine storage units available in order of preference:

- Pharmaceutical-grade (“purpose-built”) units designed by the manufacturer to either refrigerate or freeze because these units, which can be compact, under-the-counter style, or large, are specifically designed to maintain consistent temperatures for storage of vaccines in pharmacy, or lab settings. These often have:
  - Microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistance temperature detector [RTD], or thermistor); Fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperature. [Purpose-built “auto-dispensing”/automated vaccine management systems (e.g., Accuvax) are an option and guidance for these units will vary specific to their temperature and storage capabilities].
- Stand-alone refrigerators (commercial, household) are strongly recommended and considered best practice over combination units.

- Stand-alone freezers (chest, upright) are required because studies have shown that the freezer in a combination unit is unreliable for keeping frozen vaccines at the proper temperature.  
-freezer should be auto defrosting or self-defrosting.
- Combination commercial or household full size refrigerator/freezer units can be an acceptable alternative option for vaccine refrigeration only, although use of such units is discouraged due to documented problems managing vaccine in this style unit, so it can only be used under the following conditions:
  - must have separate exterior doors and should have separate temperature controls for each section.
  - the freezer compartment of this type of unit cannot be used to store vaccines so a stand-alone freezer unit is required.
- **Never Permitted**: Dormitory or bar-style refrigerators (small combination refrigerator/freezer units outfitted with one exterior door).

Consider the following to determine what size unit is required:

- There should be enough room to accommodate the largest inventory of the year – typically during flu season (or back-to-school) – without over-crowding.
- There should be space for water bottles marked "do not drink."
- Vaccine should not be stored in the door, crisper, or space created by removing the crisper bins.
- Vaccine should not be placed on the floor of the unit.
- Vaccine should not be stored near a cooling fan or vent.
- Keep vaccine at least 2-3 inches away from the walls, floor, and coils of the storage compartment to allow air space between each package, block, tray, or bin of vaccines.

#### **Vaccine Storage Unit Setup & Stabilizing Temperatures in New (& Repaired) Refrigerator/Freezer Units:**

***Prior to using any unit for vaccine storage, your local Immunization Compliance Team Member/Immunization Compliance Manager (ICM) should be made aware of all steps of this process. They will need to visit and make sure that all storage and handling guidelines are being followed prior to dispensing for patient use.***

Instructions: Before using the unit for vaccine storage, check and record the minimum and maximum temperatures once a day in the morning and the unit temperatures two times (AM and PM) on the temperature log each workday. Because it will take time to stabilize the temperature in a newly installed refrigerator/freezer, the Alabama VFC Program can require 1-2 weeks (minimum of seven consecutive days) of in-range temperatures, as monitored by a digital data logger (DDL) usually supplied by the Immunization Program, and documented on the temperature log. In the event there are less than seven consecutive days of in-range temperatures, regardless of the reason, temperature monitoring will need to continue for another seven days (minimum of 2 weeks), or until an acceptable consecutive pattern of a minimum of seven days of in-range temperatures has been established/documented and verified by your local Immunization Compliance Team Member/ICM, in order for a new (or repaired) unit to be approved to store VFC vaccine.

**NOTE:** For purpose-built "auto-dispensing"/automated (e.g., Accuvax) vaccine management systems, setup time for use will be determined by the company/manufacturer technical support team involved in the installation of a new unit (or the transfer of an existing unit), according to their requirements for establishing and stabilizing temperatures (usually 2-3 days for a new unit). The unit cannot be used until the set up (or transfer) is complete and cleared for vaccine storage and use by their technical support team.

When the aforementioned temperature monitoring/stabilization requirements for a new (transferred or repaired) unit have been met and verified by your local Immunization Team Member/ICM, your unit is ready for use. Consult your local Compliance Team Member/ICM for any questions or issues.

Refer to:

Preparing Refrigerators for Vaccine Storage Handout:

[www.alabamapublichealth.gov/immunization/assets/preparing\\_refrigerators\\_for\\_vaccine\\_storage.pdf](http://www.alabamapublichealth.gov/immunization/assets/preparing_refrigerators_for_vaccine_storage.pdf)

Refrigerator Setup for Vaccine Storage:

[www.alabamapublichealth.gov/immunization/assets/refrigerator\\_setup\\_for\\_vaccine\\_storage.pdf](http://www.alabamapublichealth.gov/immunization/assets/refrigerator_setup_for_vaccine_storage.pdf)

Freezer Setup for Vaccine Storage:

[www.alabamapublichealth.gov/immunization/assets/freezer\\_setup\\_for\\_vaccine\\_storage.pdf](http://www.alabamapublichealth.gov/immunization/assets/freezer_setup_for_vaccine_storage.pdf)

Preparing Freezers for Vaccine Storage Handout:

[www.alabamapublichealth.gov/immunization/assets/preparing\\_freezers\\_for\\_vaccine\\_storage.pdf](http://www.alabamapublichealth.gov/immunization/assets/preparing_freezers_for_vaccine_storage.pdf)

### **Vaccine Storage Unit Placement**

Place a storage unit in a well-ventilated room away from direct sunlight, leaving space between the unit, ceiling, and any wall because good air circulation around the outside of the storage unit is important. Nothing should block the cover of the motor compartment. Studies find most units work best when placed in an area with standard indoor room temperatures, usually between 20° C and 25° C (68° F and 77° F). Unit should be firm and level, with the bottom of the unit above the floor.

### **Vaccine Storage Unit Doors**

- Make sure unit doors have proper seals, open and close smoothly, and fit squarely against the body of the unit, because if not secured properly, pose a particular risk to maintaining appropriate internal temperatures of vaccine storage units.
- Consider using safeguards to ensure doors of the unit remain closed—for example, self-closing door hinges, door alarms, or door locks.

### **Vaccine Storage Temperature Controls**

Refrigerator or freezer internal thermostats should be set at the factory-set or midpoint temperature, which will decrease the likelihood of temperature excursions. Consult the owner manual for instructions on how to operate the thermostat. Thermostats are marked in various ways. In general, they show levels of coldness rather than temperatures.

### **Vaccine Storage Unit Power Supply**

- Plug in only one storage unit per electrical outlet to avoid creating a fire hazard or triggering a safety switch that turns the power off.
- No other electrical item should be plugged into the outlet that a storage unit is plugged into.
- Plug all vaccine storage units directly into a wall outlet and ensure units are not controlled by a light switch, power strip, or surge protector with an on/off switch. Check with electrician to see if a 'dedicated line' is needed for your refrigerator(s).

- Never plug storage units into power strips, surge protectors or use extension cords.
- Never plug storage units into Ground Fault Circuit Interrupter outlets (GFC). Use caution when using power outlets that can be tripped or switched off and avoid using:
  - Built-in circuit switches (may have reset buttons)
  - Outlets that can be activated by a wall switch
  - Multi-outlet power strips
- If built-in circuit switches or power strip surge protection must be used, make sure the power strip is rated to carry the maximum current as specified by the manufacturer of the refrigerator or freezer.
- Contact the unit manufacturer for any additional questions or guidance regarding circuit switches, power strips, or surge protection.
- Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged.
- Post “DO NOT UNPLUG” warning signs at outlets and on storage units to alert staff, custodians, electricians, and other workers not to unplug units.
- Label fuses and circuit breakers to alert people not to turn off power to a storage unit.
- If you have a backup battery or generator, it should be tested quarterly and serviced annually.

#### Vaccine Storage Units

Storage Unit Type	Location/Room	Brand	Model	Serial #

- Storage units should be routinely cleaned inside and kept dust-free outside.
- Keep maintenance and repair records on file and make them available to review upon request.

#### Temperature Range

Vaccines must be stored at appropriate temperatures at all times:

Refrigerators should maintain temperatures between 2° C and 8° C (36° F and 46° F)

and

Freezers should maintain temperatures between -50° C and -15° C (-58° F and +5° F)

Refrigerator or freezer internal thermostats should be set at the factory-set or midpoint temperature, which will decrease the likelihood of temperature excursions.

## Organizing and Storing Vaccine

In order to confirm vaccines are stored correctly and to minimize the risk of administration errors:

- ✓ VFC and Private vaccine storage areas/shelves should be marked “VFC” and “Private” to clearly identify vaccine stock and ensure VFC vaccines are kept separate and can be differentiated from privately purchased vaccines.
- ✓ Only use the refrigerator portion of a household combination unit for vaccine storage and avoid the use of the top shelf of the combination refrigerator when possible.
- ✓ Store frozen vaccine [Varicella, ProQuad (MMRV), etc.] in the freezer. Varicella and ProQuad (MMRV) vaccine must be stored in a stand-alone freezer that maintains a temperature between -58° F and 5° F (50° C and 15° C). Store MMR vaccine in the freezer to reduce the likelihood of a vaccine loss due to a refrigeration issue.
- ✓ Do not store food and beverages in a vaccine unit. If other medications, biological products, and/or lab specimens (e.g., blood, urine, and stool) must be stored in the same unit as vaccines, clearly label and store in separate containers or bins, away from vaccines, and place below the vaccine on a separate shelf due to risk of contamination from drips or leaks.
- ✓ Store vaccines centrally in the middle of the refrigerator or freezer unit, and away from walls to allow for proper air circulation. There should be sufficient space between rows of vaccine boxes or bins and shelving units (2-3 inches away from walls, air vents, and floor) to allow for proper air circulation. Do not over crowd refrigerators, especially during flu season.
- ✓ NEVER store vaccines near cooling vents/fans or in the door, drawers, or floor of unit. Storage unit drawers/deli crispers should be removed.
- ✓ Store each type of vaccine in a separate, labeled mesh basket/container or tray. Mesh baskets/containers are recommended over solid-sided ones because they allow for airflow. If solid-sided containers are used, they cannot have a lid.
- ✓ Store vaccines in their original packaging with lids **closed** until ready for administration. Vials and manufacturer filled syringes should always be stored in their original packaging. For certain “purpose-built”/ “auto-dispensing” units, where vaccine is stored outside of the original packaging, follow the manufacturer’s guidance for vaccine storage.
- ✓ Protect light-sensitive vaccines [e.g., HPV, Hib, IPV, MMR, ProQuad (MMRV), Varicella, and Rotavirus] by storing in their original packaging with lids closed until ready for administration.
- ✓ Vaccine and diluents with similar packaging or names should be stored on different shelves/areas of the storage unit to avoid confusion and administration errors. Label shelves and containers to clearly identify where each type of vaccine and diluent is stored.
- ✓ Diluents that are packaged with their vaccines (e.g., ACTHIB, Rotarix) must be stored in the refrigerator and should not be separated from the vaccine with which they are packed. Whenever possible, store diluent with

the corresponding refrigerated vaccine.

- ✓ Diluents that are packaged separately from their vaccines [e.g., MMR, ProQuad (MMRV), and Varicella] may be stored at room temperature or in the refrigerator, not in the freezer. Store diluents according to the manufacturers' instructions. Diluent should be clearly labeled and stored where it can be easily identified.
- ✓ Open only ONE box or vial of vaccine at a time to prevent vaccine waste. Open vials must be labeled with the date and time it was reconstituted or first opened. Loose vials or syringes may be exposed to unnecessary light, potentially reducing potency, and may be more difficult to track for expiration dates. They may also impact inventory management and increase the risk of administration errors because they may be confused with other vaccines.
- ✓ Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates. Organize vaccines so those with the shorter expiration dates are used first. Check and rotate the vaccine supply every week so the vaccine with the longest expiration date of each type is behind the vaccine with the shortest expiration date.
- ✓ Water bottles marked "Do Not Drink" should be placed on the top shelf and floor in all storage units to stabilize temperatures, including pharmaceutical grade units. Can also be placed against the back and along the walls and in the door.
- ✓ Frozen water bottles should be placed in the freezer for similar purpose as a thermal buffer (and to have available to "condition" for transport of vaccines in case of an emergency).
- ✓ Post a "DO NOT UNPLUG" sign next to the electrical outlet for all vaccine storage units and post a "DO NOT DISCONNECT" sign next to the circuit for any vaccine storage units on the circuit breaker.

### **Temperature Monitoring - Digital Data Logger (DDL)**

As a VFC provider, a working calibrated continuous TMD (DDL), with a current and valid certificate of calibration testing, is required for each storage unit containing VFC vaccine at this location (Alabama VFC program requirement).

Routine review and accessibility of temperature data are critical for determining whether vaccine has been properly stored and for assessing usability of vaccine involved in a temperature excursion. To meet VFC program requirements, the temperature monitoring device (primary and back up) must also be equipped with:

- A temperature probe
- An active temperature display that can be easily read from outside of the unit
- The capacity for continuous monitoring and recording and the data to be routinely downloaded

### **Primary DDL**

The Alabama VFC Program provides the primary DDL to VFC providers initially upon enrollment, and continually, as long as the provider meets program requirements. DDLs provide the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a "temperature excursion").

If the primary DDL supplied by the VFC Program malfunctions or expires, contact your Immunization Compliance Team Member/Immunization Compliance Manager (ICM) for a replacement. Refer to the Immunization Field Staff

Map: <https://www.alabamapublichealth.gov/immunization/assets/immunizationstaffmap.pdf> or call the Alabama VFC Program/ADPH - Immunization Division at #800-469-4599.

**NOTE:** The Alabama VFC Program requires providers to download primary DDLs weekly. Providers may print the temperature download reports and/or save information to a computer (back up required if only saving to computer).

### **Backup DDL**

Backup data loggers are required to be purchased/supplied by the VFC provider and to be on hand for immediate use (e.g., primary DDL malfunction, emergency vaccine transport).

NOTE: Dedicated DDLs (i.e., Fridge-Tag/Freezer-Tag) are required for the refrigerator and freezer (each) and should have a different calibration date from the primary DDL.

Step-By-Step Guide to Selecting and Using a Data Logger for Vaccine Inventory

[www.alabamapublichealth.gov/immunization/assets/dataloggerflyer\\_wvfclogo.pdf](http://www.alabamapublichealth.gov/immunization/assets/dataloggerflyer_wvfclogo.pdf)

Alabama Data Logger Guidelines

[www.alabamapublichealth.gov/immunization/assets/dataloggerguidelines.pdf](http://www.alabamapublichealth.gov/immunization/assets/dataloggerguidelines.pdf)

Fridge-Tag/Freezer-Tag Operating Manual (Protocol)

[www.alabamapublichealth.gov/immunization/assets/dataloggerprotocol.pdf](http://www.alabamapublichealth.gov/immunization/assets/dataloggerprotocol.pdf)

### **DDL Requirements**

- ❖ DDL probe (bio-safe glycol-encased) should be “properly” placed upright in a central area of the unit directly with the vaccines to properly measure vaccine temperature.
- ❖ DDL probe should NEVER be placed in the doors, near or against the walls, close to vents, or on floor of unit.
- ❖ DDL display is securely attached to the outside of the storage unit.
- ❖ Backup DDL’s glycol bottle/probe may be placed in storage unit, if it is clearly labeled as backup, and is not plugged into the DDL display. Place it in a plastic bag so that it is not mistakenly plugged into the primary data logger. This will allow it to always be at the proper temperature in case you need to use it quickly. Probes and cords are calibrated specifically to the logger and are not interchangeable.
- ❖ DDL must have a current and valid Certificate of Calibration - provides confidence DDL is measuring temperatures accurately: certificate must contain the model number, serial number, date of calibration, and measurement results indicating the unit passed testing.
- ❖ Certificate of Calibration should be filed in a readily accessible area to be presented to ADPH immunization local field staff [Immunization Compliance Team Member/Immunization Compliance Manager (ICM)] for review.
- ❖ DDL should be replaced on or before the expiration date listed on the device.

## Digital Data Loggers:

Primary			
Model Device Name:	Serial Number:	Calibration Expiration Date:	Location:

Backup			
Model Device Name:	Serial Number:	Calibration Expiration Date:	Location:

For Devices with Auto-Alerts: Outline below (or attach) the practice's protocol for responding to temperature excursions after the practice is closed. Consider implementing a phone tree. Ensure staff safety is addressed (e.g., for alerts after dark).

### Auto-Alert Notifications Sent to Staff

Contact Person(s): Phone/Text/ E-mail \_\_\_\_\_

**Note:** Guidance for purpose-built "auto-dispensing"/automated vaccine management systems will vary specific to their temperature and storage capabilities.

### Temperature Monitoring Documentation

To maintain awareness of storage unit temperatures and ensure that vaccines are being stored at appropriate temperatures at all times, VFC providers are required to:

- Check and document the MINIMUM and MAXIMUM temperatures once daily in the morning (AM) on the temperature log (Alabama VFC requirement) before opening the unit door.
- Check and document that the CURRENT refrigerator and freezer temperatures are in range on the temperature log twice (AM and PM) daily (Alabama VFC requirement), every day the office is open - once in the morning when the clinic opens and again before leaving at the end of the workday, including the date and time of each reading, and initials of the staff who checked and recorded the readings.
- NOTE: There should normally be a check **✓** on the DDL display at all times. If there is an **X** on the display at any time, there is an issue with temperatures that needs to be addressed immediately!
  - Document temperatures on the VFC temperature monitoring log even if the clinic uses monitoring systems that alarm or send other notifications if temperatures go out of range.
  - Post temperature logs on the storage unit door or nearby in an accessible location.
  - Temperature Logs:  
Refrigerator temperature log (Fahrenheit)

[www.immunize.org/catg.d/p3037f.pdf](http://www.immunize.org/catg.d/p3037f.pdf)

Refrigerator temperature log (Celsius)

[www.immunize.org/catg.d/p3037c.pdf](http://www.immunize.org/catg.d/p3037c.pdf)

Freezer temperature log (Fahrenheit)

[www.immunize.org/catg.d/p3038f.pdf](http://www.immunize.org/catg.d/p3038f.pdf)

Freezer temperature log (Celsius)

[www.immunize.org/catg.d/p3038c.pdf](http://www.immunize.org/catg.d/p3038c.pdf)

- Maintain all completed temperature logs for three years and make them available to ADPH local field staff [Immunization Compliance Team Member/Immunization Compliance Manager (ICM)] upon request for review at VFC site visits. This includes the paper temperature logs used to record twice daily temperatures, downloaded/printed DDL reports.
- Download and review temperature data from the DDL ***weekly*** and print (and/or save and back up) the report. Also, review storage unit temperature readings for changes in temperature trends that might require action. If there appears to be any fluctuation in temperature, troubleshoot the problem based on additional information, manufacturer manuals, and/or your office storage and handling SOPs.
- Download and review the temperature data from the DDL every time an alarm is triggered (X on the display) or the minimum/maximum reading indicates there have been out of range temperatures.

### **Safeguarding Vaccines - Handling and Reporting Out-of-Range Temperature Excursions**

Any temperature reading outside the recommended ranges is considered a temperature excursion. Documented temperatures should never be rounded. For example, if the temperature of a refrigerated storage unit is 46.1°F, the vaccine is out of range; adhere to the temperature excursion guidance. If temperature is 46°F, the vaccine is within range and has not experienced a temperature excursion.

When an out-of-range temperature is identified, **immediate** action is required to be taken to assess the situation and to prevent vaccine spoilage and loss. Correct obvious problems/check the basics, including:

- Power supply/plug
- Unit door (if ajar, close)
- Thermostat settings (do not adjust the temperature control, add ice packs, or otherwise attempt to cool a refrigerator quickly, as this may lead to overcompensation and freezing. For detailed guidance on adjusting storage unit temperature to the appropriate range, refer to the section “Vaccine Storage and Temperature Monitoring Equipment,” in CDC’s Vaccine Storage and Handling Toolkit)

### **Power Outage**

In many cases, it is better to leave the vaccine during a power outage rather than move it. If the building has temporarily lost electrical power or scheduled outage, check with the building maintenance or the power company to learn if a time for the restoration of power can be determined. If power outage due to weather emergency/natural disaster and time frame unknown, be prepared to follow guidance for transporting vaccine to backup/alternate location.

Short-term power outage (2 hours or less)

Long-term/extended power outage (greater than 2 hours)

- Do not open the refrigerator or freezer door until the power outage is resolved and the temperature inside the unit is within the normal range. If the outage occurs during business hours, note the time of the power failure.
- Once power is restored, note the time and monitor temperatures. If temperatures are not in range, follow temperature excursion guidance in Section C of this document.

### **Vaccine Storage Unit Malfunction/Failure**

- Keep doors shut and evaluate situation. Keep calm.
- For temperatures not in range, follow temperature excursion guidance in Section C of this document.

If the storage unit has failed, implement the emergency vaccine storage and handling procedures per the information contained in the Emergency Response Plan and in Section E of this document.

In general, vaccine manufacturers analyze information about the magnitude of the temperature excursion and the total amount of time that temperatures were out of range, as well as information about the vaccine in question, to determine whether a vaccine is likely to still be viable/usable.

### **Temperature Excursion**

Never allow vaccines to remain in a nonfunctioning unit following a temperature excursion.

- Take **immediate** action to respond to any out-of-range temperatures
- Refer to the following information, also contained in the step-by-step guidance ***“Handling a Temperature Excursion in Your Vaccine Storage Unit”*** enclosed in this section, which includes contact information for vaccine manufacturers.

## **NOTIFY → DOCUMENT → CONTACT → CORRECT**

CDC recommends the following steps in the event of a temperature excursion (provider must document all excursions and actions taken):

- 1) Any staff who notices a temperature excursion on the DDL display (X) or hears an alarm should notify the primary vaccine coordinator and/or backup vaccine coordinator immediately (or report the problem to a supervisor if coordinators unavailable);
- 2) Suspend vaccine administration and ***quarantine*** exposed vaccines and notify staff by labeling the vaccines “DO NOT USE” until proper guidance is obtained (do not discard these vaccines);
- 3) Place exposed vaccines in another unit, separate from other vaccines, where they can be stored under proper conditions - temperature monitored with a DDL registering within normal range. Never allow vaccines to remain in a malfunctioning unit for an extended period of time;
- 4) Download/print out the DDL temperature log and be prepared to provide the vaccine manufacturers with documentation and DDL data so they can offer you the best guidance on whether to use affected vaccines and for information about whether patients will need to be recalled for revaccination;

- 5) Primary vaccine coordinator, backup vaccine coordinator (supervisor, or person reporting the problem) should document the event with the following information:
  - a) date and time of the temperature excursion
  - b) Storage unit temperature (as well as room temperature if available), including minimum/maximum temperatures during the time of the event
  - c) Name of the person completing the report
  - d) General description of what happened
  - e) Length of time vaccine may have been affected
  - f) Inventory of affected vaccines
  - g) List of items in the unit (including water bottles) other than vaccines
  - h) Any problems with the storage unit and/or affected vaccines before the event
  - i) Other relevant information
- 6) Contact vaccine manufacturers to obtain documentation supporting the viability or verifying the non- viability of the vaccine (for a complete list of manufacturers and corresponding vaccine products, see: [www.immunize.org/resources/manufact\\_vax.asp](http://www.immunize.org/resources/manufact_vax.asp)); and
- 7) Contact ADPH immunization local field staff [Immunization Compliance Team Member/Immunization Compliance Manager (ICM)], or if unable to reach local field staff, contact the ADPH Immunization VFC Program at #800-469-4599 to report the vaccine excursion and provide a copy of that documentation supporting the viability or verifying the non-viability of the vaccine including the results on the final disposition of affected vaccines (e.g., shortened expiration date per manufacturer, discarded, or returned)



Source: [www.cdc.gov/vaccines/hcp/admin/storage/downloads/temperature-excursion-508.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/temperature-excursion-508.pdf)

#### D. VACCINE RECEIVING PROCEDURES

Staff receiving shipments must notify the primary vaccine coordinator and/or backup vaccine coordinator as soon as a vaccine shipment arrives. Staff involved in receiving vaccine deliveries should be trained to be familiar with procedures for handling vaccine shipments. Practice assumes responsibility for all VFC vaccine shipped to its site. Staff must NEVER reject vaccine shipments from FedEx or UPS. If you receive a shipment in error that is not for your clinic, store appropriately and contact the immunization VFC program.

When receiving vaccine shipments, staff designated to sign for/receive vaccine shipments should:

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- Inspect shipments immediately upon arrival to verify that the temperature during transport was within range, and that the vaccines being delivered match those listed on the packing slip.
- Verify that the packing slip agrees with the content of the shipment. Date and sign packing slip and keep it for your records. Keep shipping invoices for vaccine received through the VFC Program for a minimum of 3 years.
- Most vaccines are shipped from McKesson Specialty Distribution. Freezer stable vaccines, Varicella and ProQuad (MMRV) are directly shipped by the manufacturer, Merck.
- Open vaccine shipping containers/packages immediately upon arrival, inspect for damage, check packing slip and compare to contents of shipment (vaccine, NDC, amount, diluent, brand, lot numbers, expiration dates) to verify that what you received matches the packing slip and what was actually ordered.
- Upon receipt of refrigerated vaccines, check the enclosed temperature monitor for shipments sent from McKesson. If temperature monitors indicate a possible temperature deviation, mark the vaccine "do not use," immediately store it in the refrigerator and contact the manufacturers of the vaccines that have been received. Once you have notified the manufacturers to inquire about vaccine stability, notify your Immunization Compliance Team Member/Immunization Compliance Manager (ICM). If necessary, they will notify the VFC Vaccine Manager in the ADPH Immunization Office in Montgomery.
- Upon receipt of frozen vaccines direct ship from Merck, which may NOT be packed with temperature indicators, instead, they come with a shipper insert that identifies the allowable shipping time. Check the packing slip's shipping date to determine how long the vaccines were in transit. Varicella shipments can be sent in 2-day or 4-day boxes. ProQuad (MMRV) shipments are always shipped in a 24-hour box.  
 -If the shipment arrived beyond the allowed time, mark the vaccine "do not use", store it in the freezer, the provider should then contact Merck Order Management Center at (800-637-8579) the **same day** and provide a summary regarding the packing slip. Merck is responsible for replacing this vaccine. Merck should send a packing slip for the provider to return the vaccine. Provider should not enter this as an order (so the Alabama VFC program will not be billed twice). Merck should handle their reshipment and all necessary reports. Also, notify the VFC Vaccine Manager at #800-469-4599 in the ADPH Immunization Office in Montgomery.
- The lid of the frozen vaccine box contains diluent. Remove the diluent from the lid before you discard. Diluent can be stored in the refrigerator or at room temperature, but not in the freezer.
- Report to the immunization VFC program **immediately same day** shipment is delivered, if any of the following conditions exist:
  - vaccine shipment has temperature monitors that are out-of-range, or a warm indicator is activated
  - shipment contents and the packing slip do not match
  - shipping containers/packages are damaged
- Vaccines are then immediately stored at appropriate temperatures according to VFC requirements.

- Place vaccine in the refrigerator/freezer designated for vaccine storage immediately after an inventory of the shipment is completed.
- Contact the VFC Vaccine Manager at #800-469-4599 in the ADPH Immunization Office in Montgomery immediately for guidance if there are any concerns or inaccuracies with the vaccine order.
- Examine container and contents for physical damage, if the package and contents ARE NOT damaged – continue unpacking. If, the package or contents ARE damaged – immediately contact VFC Vaccine Manager.
- Check cold chain temperature monitors to see if temperatures are within the recommended range.
  - Temperature monitors ARE within range – continue unpacking
  - Temperature monitors ARE **NOT** within range – immediately:
    1. Note the date, time and temperature monitor reading,
    2. Label the vaccine “Do Not Use” and store under proper conditions, and
    3. Contact manufacturers of the vaccines that have been received. Once you have notified the manufacturers to inquire about vaccine stability, notify your Immunization Compliance Team Member/Immunization Compliance Manager (ICM) to inform them about the excursion. If necessary, they will notify the VFC Vaccine Manager in the ADPH Immunization Office in Montgomery.
- Crosscheck contents and expiration dates with the invoice. If there are any discrepancies, record and contact VFC Vaccine Manager at #800-469-4599 in the ADPH Immunization Office in Montgomery.
- Check the packing list to determine how long the vaccine was in transit. If the package was in transit more than 24 hours, contact VFC Vaccine Manager at #800-469-4599 in the ADPH Immunization Office in Montgomery.

#### **E. PROCEDURE FOR VACCINE IN THE EVENT OF AN EMERGENCY**

In the event of an emergency (e.g., unit malfunction/mechanical failure, power outage, weather/natural disaster, or human error) that might affect vaccine viability, consult/review your practice’s VFC ‘**Emergency Response Plan**’ (document required/completed for VFC enrollment).

The Emergency Response Plan, which should be posted on/around vaccine storage units, contains the information, including backup/alternate vaccine storage location, needed for staff to take the appropriate actions in these situations and all staff should be familiar with the location and content of that document.

#### **Vaccine Transport - Emergency**

Vaccines should not be routinely transported. Emergency transport involves relocating vaccines to protect them when the ability to store vaccines is compromised.

If possible/time-permitting, seeking permission from the VFC/Immunization Program is preferred before moving VFC vaccine, even to your backup/alternate storage location. If instructed, or it is determined best to move/transport vaccine to your backup/alternate location, this location CANNOT be a private home.

To properly maintain the “cold chain” and ensure vaccine potency is protected at all times during transport; refer to the instructions “Packing Vaccines for Transport during Emergencies”:

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

Vaccines should only be transported using appropriate packing materials that provide the maximum protection and your facility should have a sufficient supply of these materials needed for vaccine transport of your largest annual inventory. Obtain and store an adequate number/amount of appropriate packing containers and pack out materials needed for safe transport.

### **Vaccine Transport Supplies**

The following supplies are required to be in stock/on-site to transport vaccines safely in an emergency:

- Portable vaccine refrigerator/freezer units (preferred option).  
Note: Frozen vaccine should never be transported except in an emergency and with prior approval.
- Hard-sided insulated qualified containers (do not use commercially available soft-sided food or beverage coolers because most are poorly insulated). Separate packing containers for refrigerator stored vaccines and freezer stored vaccines. Label outside of container 'Must Store in Refrigerator' or 'Must Store in Freezer.'
- Insulating pack out materials such as corrugated **cardboard** and **bubble wrap** (enough to form two layers per container).
- Frozen water bottles that have been "conditioned" before packing refrigerator vaccine (never place refrigerator vaccine directly on frozen water bottles). To transport frozen vaccine, frozen water bottles should be placed in the container (dry ice is not recommended/should NOT be used for the transport of frozen vaccines - it is too cold).
- DDLs for each container (vaccines must be transported using a DDL near the vaccine to monitor the temperatures in transport containers to ensure safety of vaccine).

### **Vaccine Transport Instructions**

- Contact the backup/alternate location listed on your VFC 'Emergency Response Plan' document to ensure their power is functional and to assure your vaccine can be appropriately stored. If they do not have power or enough space [their unit(s) must accommodate the amount of vaccines currently in storage] to store this vaccine, find another reliable location.
- Quickly inventory VFC vaccine stock, package for transport, and label as "VFC vaccine."
- Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution.
- When transporting vaccines in vehicles, use the passenger compartment not the trunk.
- Stay with the vaccines at all times during transport and promptly place into appropriate storage units upon arrival.
- Record the time and temperature when vaccine was removed from the storage units and placed in the containers at the beginning and end of the transport.

## F. PROCEDURE FOR VACCINE ORDERING

### VFC Vaccine

Effective January 9, 2023, all VFC functions including enrollment, inventory, vaccine ordering, returns, and wastages will be completed through the Vaccine Operating Management System (VOMS) within ImmPRINT. Only these three designated provider staff: Site Administrator, Primary Vaccine Coordinator, and Backup Vaccine Coordinator, will be able to view VOMS for vaccine ordering within ImmPRINT. If changes occur in any of these three staff positions, the information must be updated in ImmPRINT by assigning users on the Staff List.

See: [www.alabamapublichealth.gov/immunization/vaccines-for-children.html](http://www.alabamapublichealth.gov/immunization/vaccines-for-children.html) for VOMS instructions on:

- Assigning Users
- VFC Enrollment-Provider Profile
- VFC Ordering

### VFC Flu Vaccine

Flu Pre-Book process will also be completed through the Flu Pre-book widget in VOMS within ImmPRINT.

### VFC Inventory

Complete a physical inventory of all vaccines in the refrigerator(s) and freezer(s), checking expiration dates at least monthly and before placing an order. Recommend conducting an inventory as close to the time of ordering as possible. Ensure that every VFC vaccine dose is accounted for.

- ❖ Orders are submitted according to clinic-based eligibility data, vaccine usage, and take into account the inventory in stock.
- ❖ Orders should be placed with sufficient inventory on hand to allow time for order processing and vaccine delivery. Vaccine orders usually arrive within one to two weeks, but there can be delays.
- ❖ Order monthly and stock only enough vaccine to meet patient needs/maintain a 30-day supply.
- ❖ Storing a larger volume than needed increases the risk of wasting vaccines if they expire before they can be used or they are compromised in some way (e.g., due to mechanical failure of a storage unit).
- ❖ All vaccine orders are reviewed by the VFC Program and should adjustments be necessary, the provider will be contacted.
- ❖ Every VFC vaccine dose should always be accounted for, and providers may be held financially responsible for vaccine doses not accounted for or lost due to negligence.
- ❖ If a practice runs out of vaccine due to unforeseen circumstances, call the VFC Vaccine Manager to discuss a request to place an order.
- ❖ Contact the VFC Vaccine Manager with ADPH Immunization at #800-469-4599 to update any changes in shipping address or practice operating hours to avoid receiving vaccine shipments when the clinic is closed, or the staff is not available.

❖ **Non-Routine Vaccine Availability**

Non-routine vaccines include the following listed below:

COVID-19

Dengue

Meningococcal Group B (MenB)

Maternal Respiratory Syncytial Virus (RSV)

Mpox

Pneumococcal Polysaccharide Vaccine (PPSV23)

A process for referral or another alternative for making non-routine vaccines available for VFC eligible patients. Providers can maintain a limited amount of the non-routine vaccines on site or have an alternate protocol that ensures VFC-eligible patients have access to these vaccines when applicable.

Provider's referral location or alternate plan:

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**G. PROCEDURE FOR INVENTORY CONTROL (e.g., stock rotation)**

Proper vaccine inventory management is essential for appropriate vaccine ordering and stock rotation, and ensures your practice has the vaccines your patients need.

Documenting vaccine inventory in ImmPRINT is a useful tool to assist with monitoring vaccine supply and expiration dates. Providers must document their vaccine inventory in VOMS within ImmPRINT.

See: [www.alabamapublichealth.gov/immunization/vaccines-for-children.html](http://www.alabamapublichealth.gov/immunization/vaccines-for-children.html) for VOMS instructions on inventory.

For instructions on how to add new inventory, new lot request, and delete inventory, refer to the ImmPRINT Manual: [www.alabamapublichealth.gov/immunization/immprint-manual%20.html](http://www.alabamapublichealth.gov/immunization/immprint-manual%20.html)

Prior to ordering vaccine, providers must complete a physical inventory of all vaccines in the refrigerator(s) and freezer(s), checking expiration dates at least monthly to ensure that every VFC vaccine dose is accounted for.

**Stock Rotation and Removal**

Primary vaccine coordinator, backup coordinator (or other designated staff), should rotate vaccine and diluent stock and check for expired doses regularly/monthly, as well as each time your facility receives a vaccine delivery, which will ensure that vaccines expiring sooner are used first.

Arrange stock for each vaccine type so that doses with the earliest expiration dates are placed in front of those with later expiration dates:

- Place vaccine with shortest expiration date in front (date closest to today's date).
- Place vaccine with longest expiration date in back (date furthest from today's date).

Any expired vaccines and diluents should be removed immediately to avoid inadvertently administering them.

## H. PROCEDURE TO HANDLE VACCINE WASTAGE

### Vaccine Wastage

All spoiled, expired, or wasted vaccines must be accounted for and reported through VOMS within ImmPRINT. Remove any spoiled/expired/wasted vaccine from storage units with viable vaccine to prevent inadvertent administration. Account for wastage by reporting in VOMS, following the screen prompts. **Vaccine return labels will be emailed for eligible vaccine returns.** Wastage and expiration of VFC vaccines should be less than 5% annually. See: [www.alabamapublichealth.gov/immunization/vaccines-for-children.html](http://www.alabamapublichealth.gov/immunization/vaccines-for-children.html) for VOMS instructions on wastage.

Alabama VFC Program Fraud, Abuse, and Wastage Policy:

[www.alabamapublichealth.gov/immunization/assets/vfcfraudandabusepolicy.pdf](http://www.alabamapublichealth.gov/immunization/assets/vfcfraudandabusepolicy.pdf).

Alabama VFC Vaccine Replacement Policy & Accountability Worksheet (revised 8/28/22):

[https://www.alabamapublichealth.gov/immunization/assets/al\\_vfc\\_replacement\\_policy.pdf](https://www.alabamapublichealth.gov/immunization/assets/al_vfc_replacement_policy.pdf)

### Vaccine Wastage Disposal

Vaccines are considered wasted if they have been opened or damaged and cannot be administered to patients. Dispose of wasted VFC vaccine that cannot be returned to McKesson according to usual medical bio-safety procedures/sharps container disposal at the provider site.

Reasons vaccines should be discarded on site (not physically returned) appropriately as medical waste include:

- vaccine drawn into a syringe but not administered
- manufacturer-filled syringes that have been activated
- vaccine opened in error
- error in vaccine reconstitution
- vaccine whose sterility has been compromised by the vial being dropped or broken
- multi-dose vials of vaccine that have been opened with some doses administered or that have expired

### Vaccine Returns

See: [www.alabamapublichealth.gov/immunization/vaccines-for-children.html](http://www.alabamapublichealth.gov/immunization/vaccines-for-children.html) for VOMS instructions on returns.

- 1) Expired vaccine - any vaccine with an expiration date that has passed (must be returned within 6 months of expiration date).
- 2) Spoiled vaccine - any vaccine exposed to temperatures that exceed limits of approved cold chain procedures and is deemed non-viable or spoiled according to vaccine manufacturer guidance due to a temperature excursion.

The Immunization VFC Program will review the request and, upon approval, will email a shipping label. Upon receiving the shipping label, vaccine should be packed to prevent vial breakage, printed copy of return form included in the box, and shipped to McKesson within six months of spoilage or expiration.

DO NOT return:

- viable vaccine
- used syringes with or without needles, doses drawn up but not administered, manufacturer-filled syringes that have been activated
- open or broken vials
- multi-dose vials with some doses administered
- diluent
- privately purchased vaccines

## I. STAFF TRAINING AND DOCUMENTATION ON VACCINE MANAGEMENT, STORAGE, AND HANDLING

Vaccine storage and handling practices are only as effective as the staff that implements them. Staff that is well trained in general storage and handling principles and organization-specific storage and handling standard operating procedures (SOPs) is critical to ensuring vaccine supply potency and patient safety.

This document highlights key duties of designated vaccine management staff. However, all staff working with vaccines should be familiar with VFC requirements and guidelines and all staff members who receive vaccine deliveries, as well as those who handle or administer vaccines, should be trained in vaccine-related practices and procedures and be familiar with the content of this vaccine management plan.

Primary vaccine coordinator responsibilities may be completed by the coordinator or delegated to appropriate staff. If delegated to appropriate staff, the primary vaccine coordinator should ensure that designated staff is adequately trained.

For staff training purposes, if the Primary Vaccine Coordinator or the Backup Coordinator is replaced, notify your ADPH immunization local field staff [Immunization Compliance Team Member/Immunization Compliance Manager (ICM)]. Refer to the Immunization Field Staff Map:

<https://www.alabamapublichealth.gov/immunization/assets/immunizationstaffmap.pdf> or call the Alabama VFC Program/ADPH - Immunization Division at #800-469-4599.

### Staff Training

The Primary Vaccine Coordinator and Backup Vaccine Coordinator are **required** to complete the following two Web-based training courses annually (courses are updated annually):

1. You Call the Shots: Module 10, Storage and Handling
2. You Call the Shots: Module 16, Vaccines for Children Program

Find the modules at: [https://www.cdc.gov/immunization-training/hcp/you-call-the-shots/?CDC\\_AAref\\_Val=https://www.cdc.gov/vaccines/ed/youcalltheshots.html](https://www.cdc.gov/immunization-training/hcp/you-call-the-shots/?CDC_AAref_Val=https://www.cdc.gov/vaccines/ed/youcalltheshots.html)

This training is also recommended for all staff with VFC program and/or vaccine storage and handling responsibilities.

### Training Documentation

NOTE: To receive credit for the required courses & obtain a printed certificate of completion - required as proof upon VFC enrollment, annually with provider profile, and at VFC compliance site visits, set up an account on CDC TRAIN.

In addition, the primary and backup vaccine coordinators must review CDC's Storage and Handling Toolkit:

[www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)

Other Training Resources:

Skills Checklist for Vaccine Administration

[www.immunize.org/catg.d/p7010.pdf](http://www.immunize.org/catg.d/p7010.pdf)

Key Vaccination Resources for Healthcare Professionals

[www.immunize.org/catg.d/p2005.pdf](http://www.immunize.org/catg.d/p2005.pdf)

Clinic Tools

[www.immunize.org/clinic/](http://www.immunize.org/clinic/)

#### J. REVIEW DATE WITHIN THE LAST 12 MONTHS

Staff responsible for the content of the Vaccine Management Plan must review the plan and sign and date annually. Primary Vaccine Coordinator and Backup Coordinator signatures are always required.

In addition, when practice-specific or other changes (i.e., new employee hire, key staff changes, and best practices updates) to content occur, the log must be updated and signed.

#### K. SIGNED BY INDIVIDUAL RESPONSIBLE FOR CONTENT

##### Signature Log

By signing, all staff involved in vaccine management acknowledges they have reviewed and are familiar with the content of this plan annually (and when any changes to content occur):

Date	Print Name/Title	Signature	Annual Review	Update/Comments

(Insert more lines as needed)

Person Completing/Reviewing Plan: \_\_\_\_\_

Date: \_\_\_\_\_

Signature: \_\_\_\_\_