Purpose: To provide a unified policy for handling of vaccines to ensure viability

Storage of Vaccines
1. Maintain freezers and refrigerators within the proper temperature ranges.
   - Refrigerator -- 35-46º F. (2-8º C)
   - Freezer for varicella vaccine -- 5º F. (-15º C) or colder

Two acceptable storage units:
1. unit that has separate doors for the refrigerator and freezer compartments
2. stand-alone refrigerators and freezers

2. Place working certified thermometers in center of both the refrigerator and freezer compartments. Retain and have the traceable calibration certificate readily accessible during TVFC/AFIX visits. Follow manufacturer’s recommended schedule for recalibration of the certified thermometers. Note: A certified thermometer must meet National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards.

3. Place a temperature log on the vaccine storage unit door or nearby in a readily accessible place. Record the temperature in both compartments (refrigerator and freezer) each morning and afternoon (before close of business) on the temperature log, ensuring that refrigerator temperatures are between 35º and 46º F (2º and 8º C). The freezer temperature should be 5º F or lower (-15º C or lower). **Twice-daily manual temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used.**

4. Take immediate action to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage temperatures outside the recommended ranges. Document actions taken to rectify the situation on the temperature log including the following information: date and time temperature was found to be out of range, actions taken to correct the situation. You will then need to check the unit periodically (every 30 minutes) to ensure the temperature is within the required range again. Once this happens you will need to document the current date and time along with the amount of time the vaccine was exposed to out of range temperatures. If the temperature is still out of range after a 2 hour period, immediately move vaccine to another functional storage unit and monitor that unit to ensure temperatures meet TVFC vaccine storage requirements. **Varicella and MMR vaccines must be moved to another functional storage unit immediately in the event of a power failure or mechanical difficulty.**

5. Maintain an ongoing file of temperature logs, and store completed logs for 3 years.

6. Store ice packs in the freezer and water jugs in the refrigerator and freezer along with vaccines. This will help maintain a stable, cold temperature if the power were to fail or the doors are opened frequently. Frequent opening and closing doors can lead to marked temperature variations.
7. Store vaccines only in the central storage area of the refrigerator and freezer compartments. Never store vaccines in the door of the refrigerator or freezer. Refrigerated vaccines should always be stored far away from the freezer compartments to avoid freezing.

8. Keep all open vials of vaccine in a tray in the refrigerator. To avoid medication errors, don’t store other pharmaceuticals in the same tray.

9. Do not store food or drinks in the refrigerator or freezer where vaccines are stored.

10. Safeguard the refrigerator electricity supply. Make sure the refrigerator outlet has a safety lock-type plug.

11. Label the refrigerator, outlets, fuses and circuit breakers with information that clearly identifies the perishable nature of the vaccines and the need to keep the power supply uninterrupted. Provide contact information including staff name and 24-hr contact number.

12. Post the immediate steps to be taken in case of an interruption of power or mechanical difficulty in a clearly visible area so the staff may consult them immediately should a power interruption occur. The emergency plan should include the following: person(s) responsible for preparing and transporting vaccine (including contact information), how this person will be notified that vaccine needs to be moved if emergency arises outside of normal business hours, location that will receive vaccine, how receiving location will be notified of transport, how to pack vaccine for transport, worksheet to document vaccine involved in power or equipment failure.

**Instructions For Receiving Vaccine Shipments**

The following steps should be taken each time a vaccine shipment arrives:

1. Open transport containers immediately upon receipt.
2. Inspect vaccine for evidence of damage.
3. All discrepancies must be reported within **2 hours of receipt** to Vaccine Management at 207-4015 or 207-4308. If discrepancies are reported outside of the 2 hour window, the TVFC program could be financially liable for replacing compromised vaccines which will affect future DSHS vaccine allocations.
4. Refrigerated vaccine should be cold but not frozen; Varicella vaccine should be frozen and packed in ice packs; MMR may be cold or frozen.
5. Freeze indicator (if used) must be clear and colorless.
6. Check quantities, including diluents and lot numbers and expiration dates against the invoice.
7. Report discrepancies immediately to Vaccine Management at 207-4015 or 207-4308.
8. Store vaccines in the refrigerator; varicella in the freezer in the body of the unit, never on the doors or in closed storage bins where air cannot circulate around the vaccine.
9. Place earliest expiration dates in front of storage and use first.
10. Check expiration dates at least monthly and before placing an order.
11. For vaccine viability questions: notify Vaccine Management at 207-4015 or 207-4308, then **contact the manufacturer of the vaccine**.
12. Mark questionable vaccine, place in proper storage apart from the other usable vaccines.
Contact Vaccine Management once manufacturer makes decision about viability of the vaccines.
GSK-1-(866)-475-8222  
MedImmune- 1-(877)-633-4411  
Merck- 1-(800)-637-2579  
Novartis- 1-(800)-244-7668  
Sanofi-pasteur - 1-(800)-822-2463  
Pfizer-1-(800)-438-1985

**Vaccine Storage or Handling Mishaps**

It is important for all staff to understand the significance of reporting any violation of handling protocol or any accidental storage problems (e.g., electrical failure, placing vaccine in the refrigerator instead of the freezer). It is everyone’s responsibility to make sure the vaccines administered to patients are properly handled and stored to maintain viability. If vaccine storage or handling mishaps occur the following procedures will be followed:

- Mark the vaccines in question and transfer to a working refrigerator or freezer as quickly as possible.
- Record the temperature inside the refrigerator and freezer at the time of discovery.
- Record the length of time the vaccine may have been exposed to non-optimal temperatures.
- Call Vaccine Management at 207-4015 or 207-4308 then contact manufacturer of the vaccine. Please see # 12 above.

**Vaccine Handling Procedures**

1. Indicate on the label of each vaccine the date it was opened. Do not open more than one vial of a particular vaccine at a time.
2. Open multi-dose vials of vaccines that contain a bacteriostatic agent are viable until the expiration date unless contaminated.
3. Vaccine with an expiration date printed as a month and year will expire at the last day of that month.
4. Check expiration dates regularly.
5. Contact TVFC program within 90 days of expiration of vaccines so they may be recovered and moved to another provider by Metro Health.
6. Never administer expired vaccines. Promptly remove expired vaccine from inventory to avoid accidental use. Contact Vaccine Management.
7. The following vaccines should be discarded after reconstitution:
   - MMR vaccine, if not used within 8 hours.
   - PedvaxHIB (PR-OMP) vaccine, if not used within 24 hours.
   - Varicella vaccine if not used within 30 minutes.
8. Varicella vaccine must be stored frozen at the average of 5º F (-15º C) or colder until it is reconstituted. If varicella vaccine has been thawed, but has not been reconstituted, the vaccine must be used within 72 hours as long as the vaccine is stored at 8º C (46º F) or colder.
9. Diluents may be stored in the door of the refrigeration unit to provide extra insulation for stored vaccines like bottles of water. Diluents for MMR and varicella are preferred to be stored cool, because warm diluent may inactivate these vaccines. Diluents should never be frozen; especially those containing adjuvant.

**Vaccine Transfers**

1. Vaccine transfers between providers is prohibited unless approved by SAMHD TVFC Vaccine Manager (210) 207-4015 and TVFC Coordinator (210) 207-3974.