Tennessee Immunization Program (TIP)

Temperature Monitoring and Excursion Guidance for Non-Health Department Facilities
# Table of Contents

Section 1. Vaccine Storage and Monitoring Equipment ............................................................... 2
   A) Vaccine Storage Units ...................................................................................................... 2
   B) Additional Requirements for a Storage Unit ....................................................................... 2
   C) Continuous Temperature Monitoring Devices, or Digital Data Loggers ......................... 3
   D) Back-up Digital Data Logger ................................................................................................. 4

Section 2. Temperature Monitoring Procedures .......................................................................... 5
   A) Daily Temperature Monitoring Procedures ....................................................................... 5
   B) Weekly Vaccine Monitoring .................................................................................................. 7
   C) Monthly Vaccine Monitoring ................................................................................................. 7

Section 3. Temperature Excursions (TEs)....................................................................................... 9
   A) Definitions ................................................................................................................ .............. 9
   B) Reportable TE Procedures .................................................................................................. 10

Section 4. Probation ....................................................................................................................... 13
   A) Definition ......................................................................................................................... 13

Section 5. Resources and References .......................................................................................... 15
Section 1. Vaccine Storage and Monitoring Equipment

Proper use of good quality vaccine storage and temperature monitoring equipment is the best way to assure you do not waste or administer vaccine that has been compromised due to inappropriate storage conditions.

A) Vaccine Storage Units

1. The Tennessee Immunization Program (TIP) requires the use of stand-alone refrigerator and freezer units and strongly recommends the use of purpose-built or pharmaceutical/medical grade units. Studies conducted by the CDC have demonstrated that combination units are not capable of reliably maintaining appropriate vaccine storage temperatures, even when only using one compartment of the unit.
   a. Stand-alone storage units are self-contained units that either only refrigerator or freeze. These units can vary in size, but must be suitable for vaccine storage.
   b. Providers are strongly encouraged to use a stand-alone automatic defrost freezer. If a provider decides to use a stand-alone manual defrost freezer, an on-site back-up freezer also must be approved to store vaccine when defrosting the main freezer unit.

2. Before purchasing a new vaccine storage unit, we recommend contacting TIP to ensure that the unit meets all current VFC program requirements.

3. Dormitory or bar-styled refrigerators and freezers are prohibited for storing VFC vaccines at any time.

4. Follow manufacturer maintenance schedules provided in the owner manual.

B) Additional Requirements for a Storage Unit

1. Enough room to store the largest vaccine inventory at the busiest point in the year, without crowding (e.g., flu and back-to-school seasons)

2. Protect the power source for all vaccine storage equipment, by means of warning labels, such as “Do Not Disconnect,” posted at the electrical outlets, circuit breakers, and back-up generators. Consider appropriate policies and protocols.

3. Enough room for a “thermal ballast” – water bottles in the refrigerator and frozen water bottles in the freezer – that can function to stabilize the temperature during routine use and brief power outages.
C) Continuous Temperature Monitoring Devices, or Digital Data Loggers

1. Each storage unit is required to have a certified calibrated digital data logger (DDL) with the following features:
   a. Continuous monitoring and recording capabilities
   b. Record in Celsius
   c. Capacity for temperature data to be routinely downloaded
   d. An active display that is placed on the outside of the unit to allow staff to read temperatures without opening the door
   e. A detachable, buffered probe
   f. An alarm for out-of-range temperatures
   g. Low battery indicator
   h. Accuracy of +/- 0.5°C (1°F)
   i. Memory storage of at least 4000 readings
   j. User programmable logging interval (or reading rate)

Each DDL must have a current, valid Certificate of Calibration Testing.

2. Purpose: Provides detailed information on all temperatures recorded at preset intervals. Temperatures are considered official and accurate, barring failure of the device. All temperature excursions (TEs) are defined by the DDL, and these are the basis of all decisions made about vaccines after a TE.

3. Settings: DDLs should be preset to record temperatures every 15 minutes, in Celsius. The alarm triggers (see table below) should be set to indicate TEs for the refrigerator when it is too cold for 15 consecutive minutes or too warm for 60 consecutive minutes. Freezer alarms should be set to show a too warm TE that occurs for 60 consecutive minutes. Refer to procedure guidance for definitions of when a TE should be reported. Providers should refer to the manufacturer’s guidance on how to set alarm parameters for their DDL.

<table>
<thead>
<tr>
<th>Unit type</th>
<th>Temperature</th>
<th>Duration out-of-range</th>
<th>Alarm type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerator</td>
<td>≤ 2°C (≤ 35.6°F)</td>
<td>00:15 (15 minutes)</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>≥ 8°C (≥ 46°F)</td>
<td>01:00 (1 hour)</td>
<td>High</td>
</tr>
<tr>
<td>Freezer</td>
<td>≥ -15°C (≥ 5°F)</td>
<td>01:00 (1 hour)</td>
<td>High</td>
</tr>
</tbody>
</table>

4. Most DDLs have a removable wire probe leading to the DDL. The wire should enter the unit on the hinge side, high in the corner. Tape the wire in the doorframe of the unit with thin, clear packing tape to ensure a good seal. Secure the glycol probe to the shelf in the center of the unit by using Velcro or placing it in a paper cup.

5. DDLs are required to record in Celsius.
D) Back-up Digital Data Logger

1. CDC requires VFC providers to have at least one back-up DDL on-site, with a valid and current certificate of calibration.

   **Policy Change:** Beginning January 1, 2018, min/max thermometers can no longer be used as a back-up for a DDL.

2. Purpose: To allow temperature assessments and recordings to be performed twice a day, even if the original DDL no longer works appropriately or needs calibration testing.

3. Storage: CDC recommends that the back-up DDL be stored outside of the storage unit. This frees up room in the unit for vaccines and prevents confusion if two DDLs are reading slightly different temperatures.

   ![Digital Data Loggers (DDLs)](image-url)
Section 2. Temperature Monitoring Procedures

Temperature monitoring is the primary responsibility of the Primary VFC Coordinator and/or Back-up VFC Coordinator. It is required that temperatures for each vaccine storage unit are reviewed twice a day (morning and afternoon) and the minimum and maximum temperatures are reviewed each morning. Temperature readings must be documented, as should any actions that are taken if the temperature readings are out of acceptable range. Always contact TIP for guidance prior to administering vaccine after a TE occurs.

The refrigerator should maintain temperatures between 2.0°C and 8.0°C; average target temperature is 5°C. The freezer should maintain temperatures between -50°C and -15°C. The freezer thermostat should be set at the factory-set or midpoint temperature to assure appropriate frozen storage temperatures.

A) Daily Temperature Monitoring Procedures

Regardless of the brand of the DDL, the basis of the processes outlined below should be followed to meet VFC requirements for temperature monitoring. If using a DDL other than a Fridge-tag 2L™, review the owner's manual for instructions on reviewing temperatures and downloading temperature logs. If using a Fridge-tag 2L™, tutorials are available at: https://www.tn.gov/health/cedep/immunization-program/ip/vfc/vfc-provider-guidance.html

1. Morning Procedures:
   When the clinic opens, record the temperature of each storage unit by pushing the “read” button on the refrigerators and freezers. Document the time and date of each reading, minimum and maximum temperatures for the previous day, the initials of the person who recorded the reading, and whether any new alarms were present on each unit’s Vaccine Storage Unit DDL Sign-off Sheet.
   a. Quickly scan the DDL for any symbols indicating an alarm has occurred.
   b. If a new alarm is present, refer to Section 3. Temperature Excursions (TEs) of this guide. It is important to clear alarm on DDL, this will allow you to determine if a new alarm triggers later in the day.
   c. If there are no new alarms, proceed with a brief visual inspection of the unit and correct any problems that are found:
      - Food and drinks should not be stored in a vaccine storage unit.
      - Vaccines should not be stored in the doors, drawers, or floor of a vaccine storage unit.
      - Vaccines should be stacked with at least one inch of air space between the stacks and two inches of air space between the stacks and walls of the unit, so air can circulate around the vaccines.
• Water bottles labeled “Do Not Drink” should be stored in the lowest compartment of the refrigerator and in the doors. Extra ice packs should be put in the freezer to help maintain temperatures, in case of a power outage.
• VFC vaccines should be clearly labeled and separated from privately-purchased vaccines for easy identification.

2. Afternoon Procedures:
TIP strongly recommends not waiting until the very end of a clinic day for the afternoon reading in case a problem is found and consultation is needed. We recommend recording the temperature in each storage unit by pushing the “read” button on the refrigerators and freezers an hour before closing the clinic. Document the time and date of each reading, the initials of the person who recorded the reading, and whether any new alarms were present on each unit’s Vaccine Storage Unit DDL Sign-off Sheet.

Fridge-tag 2L™ users: In order for this DDL to record a pm reading, the 2nd reading of the day must occur after 12:00PM. If the clinic closes at noon, you may either wait until 12:01PM to press the read button, or document the time of office closure in the comment section of your report.

a. Quickly scan the DDL for a symbols indicating an alarm has occurred.

b. If a new alarm is present, refer to Section 3. Temperature Excursions (TES) of this guide. It is important to clear alarm on DDL so you can determine if a new alarm triggers later in the day.

c. If there are no new alarms, proceed with a brief visual inspection of the unit and correct any problems that are found:
• Food and drinks should not be stored in a vaccine storage unit.
• Vaccines should not be stored in the doors, drawers, or floor of a vaccine storage unit.
• Vaccines should be stacked with at least one inch of air space between the stacks and two inches of air space between the stacks and walls of the unit so air can circulate around the vaccines.
• Water bottles labeled “Do Not Drink” should be stored in the lowest compartment of the refrigerator and in the doors. Extra ice packs should be put in the freezer to help maintain temperatures in case of a power outage.
• VFC vaccines should be clearly labeled and separated from privately-purchased vaccines for easy identification.

3. Documentation:
A provider using a DDL that has the ability to record twice a day readings (such as Fridge Tag and Log Tag brands), should use this function and document daily
readings on the Vaccine Storage Unit Digital Data Logger Sign-off Sheet.

a. If the DDL report is able to document the initials of the person completing the readings for the morning and afternoon readings, the sign-off sheet does not need to be used.

b. If the DDL does not have the ability to document the twice a day readings on the DDL report, document daily readings on the TIP Temperature Logs for Refrigerators and Freezers.

The VFC Program requires that DDL reports are printed and reviewed each week and maintained with temperature logs for three years.

B) Weekly Vaccine Monitoring

On the same day every week, the Primary VFC Coordinator or Back-up VFC Coordinator should review the Vaccine Storage Unit Digital Data Logger Sign-off Sheet for each unit and the DDL report, to ensure that the unit was checked twice each clinic day and that any new alarms were documented. Additionally, they should:

1. Download the DDL report.
   a. Most DDLs will alarm if disconnected from the probe for some period of time, such as 10 minutes.
2. Print the .pdf of the DDL report and sign the comments section to indicate that the weekly report was reviewed. Signatures on each day are not necessary. This is only to confirm that the report was reviewed for the week.
   a. Note any alarms on the DDL report and whether staff responded appropriately. All information about a TE, including the DDL report and any follow-up, should be filed with the temperature logs for the unit and retained for three years.
3. Review vaccine inventory and organize vaccines so that vaccines with the shortest expiration dates are in front to be used first.

C) Monthly Vaccine Monitoring

1. Visually check storage units for correct vaccine and probe placement.
2. Inspect vaccine storage units to ensure cleanliness.
3. Follow the manufacturer’s maintenance schedule for the storage units.
4. Replace the Vaccine Storage Unit Digital Data Logger Sign-off Sheet for each unit.
   a. File completed sheets with the .pdf DDL reports for each unit.
   b. These documents must be maintained for three years.
5. Review vaccine inventory and notify TIP if there is any VFC vaccine with short expiration dates (within 90 days or 3 months from the current date) that you will not be able to use prior to expiration. Vaccine inventory reconciliation must be done

Vaccine inventory reconciliation must be done
every month, even if vaccines are not ordered.
Section 3. Temperature Excursions (TEs)

A) Definitions
Temperature Excursion (TE): Any time the temperature in a refrigerator is outside the 2.0°C through 8.0°C range or the temperature in a freezer is warmer than -15°C (5°F). TIP is open 8am – 4:30pm Central Time, weekdays and closed on all state holidays. TIP must be notified as quickly as possible during business hours or on the next business morning and before any vaccine is administered, if any one of the below criteria are met:

1. Refrigerator temperature dipped below 2.0°C (36°F) for 15 consecutive minutes (or longer).
   a. Freezing temperatures below 0.0°C (32°F) quickly damages vaccine. Quick action may save vaccine if temperature begins to get too cold.
2. Refrigerator above 8.0°C (46°F) for at least 60 consecutive minutes.
3. Freezer above -15°C (5°F) for more than 60 minutes.
   b. Frost-free freezer defrost cycles may go above -15°C (5°F) for short periods. Vaccine stability data supports these types of excursions.
4. TE is part of a pattern of frequent excursions, regardless of duration.
5. You are concerned about TE even though it doesn’t meet above criteria.
B) Reportable TE Procedures

Use the flow chart below to determine if your facility experienced a reportable TE:

You may also contact TIP if the TE is part of a pattern of frequent excursions, regardless of duration, or if you are concerned about the TE even though it does meet the above criteria.
1. **Reporting a TE during Business Hours (Monday – Friday, 8:00AM – 4:30PM CST)**
   a. If the vaccine storage unit's temperature is **still out of range**:
      - Quarantine vaccine. Label the unit “Do Not Use until Further Notice.”
      - Inspect the storage unit to see if:
        1. the storage unit is unplugged
        2. the storage unit door is opened or not sealed adequately
        3. the thermostat is set at an appropriate temperature
        4. the DDL probe is located in the middle of the unit
        5. there is dust in the coils and vents
      - Download the DDL report, note how long the temperature was out of range
      - Immediately call the TIP VFC QA team at (800) 404-3006. If the call is not answered promptly, call the CEDEP main desk at (615) 741-7247 and ask the receptionist to locate someone at TIP.
        1. You will be asked to fax your DDL report to TIP at (615) 401-6829.
        2. *If instructed by TIP*, follow your Emergency Storage and Handling Plan posted on or beside the storage unit. If the storage unit cannot be used, transfer vaccine to the designated back-up location.
        3. TIP will pull a list of your VFC-funded vaccines from TennIIS, but you may be asked to fax an inventory of privately purchased vaccines. You will need to include a list of the brand names and presentation of influenza vaccines in your inventory.
        4. TIP does not follow-up on non-vaccine items (e.g. medications, Tubersol) involved in a TE.
   b. If the vaccine storage unit's temperature is **back in range**:
      - Quarantine vaccine. Label the unit “Do Not Use until Further Notice.”
      - Inspect the storage unit to see if:
        1. the storage unit is unplugged
        2. the storage unit door is opened or not sealed adequately
        3. the thermostat is set at an appropriate temperature
        4. the DDL probe is located in the middle of the unit
        5. there is dust in the coils and vents
      - Download the DDL report, note how long the temperature was out of range
      - Immediately call the TIP VFC QA team at (800) 404-3006. If the call is not answered promptly, call the CEDEP main desk at (615) 741-7247 and ask the receptionist to locate someone at TIP.
        1. You will be asked to fax your DDL report to TIP at (615) 401-6829.
        2. TIP will pull a list of your VFC-funded vaccines from TennIIS, but you may be
asked to fax an inventory of privately purchased vaccines. You will need to include a list of the brand names and presentation of influenza vaccines in your inventory.

3. TIP does not follow-up on non-vaccine items (e.g. medications, Tubersol) involved in a TE.

c. If your facility is experiencing a power outage, contact your local utility company. If restoration is expected to occur within 4 hours, do not move vaccine. The storage unit door should be kept closed and the temperature monitored. A brief TE may be less harmful than transporting vaccines. If a power outage is going to last more than 4 hours, follow your Emergency Storage and Handling Plan.

d. TIP VFC QA will gather details of the event from you and follow up with vaccine manufacturers if necessary.
   • A follow-up for each TE will be conducted by phone and an email summary will be sent that must be reviewed and kept with DDL reports for three years.
   • If the TE requires the transfer of vaccines to another location, staff will need to follow the steps for packing and monitoring vaccines detailed in the current Emergency Storage and Handling Plan posted on or near the storage unit.
   • Vaccines should not be administered until approved for use by TIP.

2. Reporting a TE after Business Hours (Monday – Friday, 8:00AM – 4:30PM CST)

   a. Quarantine vaccine. Label the unit “Do Not Use until Further Notice.”

   b. Inspect the storage unit to see if:
      • the storage unit is unplugged
      • the storage unit door is opened or not sealed adequately
      • the thermostat is set at an appropriate temperature
      • the DDL probe is located in the middle of the unit
      • there is dust in the coils and vents

   c. Download the DDL report.

   d. If the storage unit is still out-of-range, follow the Emergency Storage and Handling Plan posted on or near the unit and follow directions for evaluating the power outage. Only move vaccines if indicated; vaccines may be safer if left in place for a short power outage than if it is moved.

   e. Contact the TIP VFC QA staff immediately by the next business day.
      • If you contact TIP at (615) 741-7247 or (800) 404-3006, the call will be answered by the on-call senior epidemiologist for CEDEP, who will be able to provide basic information (contained herein) but will not provide advice on the viability of the vaccine. If vaccine must be used before TIP is open, clinic staff may directly contact the vaccine manufacturer customer service line for assistance.
Section 4. Probation

A) Definition

Probation occurs when a provider fails to report a TE by the end of the next business day.

1. If a TE is not reported and **there is vaccine loss**, the provider will be placed on probation for 6 months. This will include:
   a. Submission of weekly temperature logs to the Regional Immunization Representation (RIR) for four weeks (first month of probation).
   b. Submission of monthly temperature logs to their RIR after the first four weeks (last five months of probation). **Note**: The RIR may decide, based on their observations, to request more frequent submission or extend the time period for reviewing temperature logs.
   c. RIR will conduct an on-site education visit for the provider, Primary VFC Coordinator, and Back-up VFC Coordinator.
   d. RIR will conduct at least one unannounced storage and handling visit by the RIR. If there is a need for additional visits, the RIR will communicate with the TIP VFC QA Coordinator or Program Manager.
   e. TIP may determine that the storage unit requires service or replacement. In that case, vaccine orders will be placed on hold until verification of repair or replacement is provided. Verification can be a copy of an invoice or an email from the VFC Contact to the TIP VFC QA team noting the date of service/repair or delivery of a new storage unit. In addition, five consecutive days of in-range temperature readings must be submitted before TIP approves use of the repaired or new unit.
   f. After the 6 month probation, the provider will resume routine monitoring if in compliance. If not in compliance, the provider will be suspended from the VFC program.
   g. After 6 months of suspension, the provider will need to go through the enrollment process again to participate in the VFC Program. This will include:
      - RIR enrollment visit. Previous non-compliance issues will need to be resolved at this time.
      - If approved by the RIR, the provider will maintain the same VFC PIN.
      - RIR will conduct an unannounced storage and handling visit within 60 days of re-enrollment.
      - RIR will conduct a VFC compliance visit within 6 months of enrollment.

2. If a TE is not reported and **there is no vaccine loss**, the provider will be placed on probation for 6 months. This will include:
a. Submission of weekly temperature logs to the RIR for four weeks (first month of probation).
b. Submission of monthly temperature logs to the RIR after the first four weeks (last five months of probation). **Note:** The RIR may decide, based on their observations, to request more frequent submission or extend the time period for reviewing temperature logs.
c. RIR will conduct an on-site education visit for the provider, Primary VFC Coordinator, and Back-up VFC Coordinator.
d. TIP may determine that the storage unit requires service or replacement. In that case, vaccine orders will be placed on hold until verification of repair or replacement is provided. Verification can be a copy of an invoice or an email from the VFC Contact to the TIP VFC QA team noting the date of service/repair or delivery of a new storage unit. In addition, five consecutive days of in-range temperature readings must be submitted before TIP approves use of the repaired or new unit.
e. After the 6 month probation, the provider will resume routine monitoring if in compliance. If not in compliance, the provider will be suspended from the VFC program.
f. After 6 months of suspension, the provider will need to go through the enrollment process again to participate in the VFC Program. This will include:
   - RIR enrollment visit. Previous non-compliance issues will need to be resolved at this time.
   - If approved by the RIR, the provider will maintain the same VFC PIN.
   - RIR will conduct an unannounced storage and handling visit within 60 days of re-enrollment.
   - RIR will conduct a VFC compliance visit within 6 months of enrollment.
Section 5. Resources and References

1. CDC’s Vaccine Storage and Handling Toolkit
   https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

2. Routine and Emergency Vaccine Management Plan

3. Vaccine Storage Unit Digital Data Logger Sign-off Sheet
   https://www.tn.gov/content/dam/tn/health/documents/immunizationrequirements/Vaccine_Storage_Unit_Digital_Data_Logger_Sign-Off_Sheet.pdf

4. Celsius (°C) Temperature Logs

5. Packing Vaccines for Transport during Emergencies
   https://www.tn.gov/content/dam/tn/health/documents/immunizationrequirements/Packing_Vaccines_for_Transport_during_Emergencies.pdf