



# Tennessee Immunization Program

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Temperature Monitoring and Excursion Guidance  
for  
All Federal, State, or Local Vaccines Stored in  
Public Health Clinics

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## **Section 1. Vaccine Storage and Monitoring Equipment**

### **A) Refrigerators**

1. Health Department Standard: Free-standing refrigerators of pharmaceutical grade (including such features as a fan for circulating air through the unit).
2. Purpose: Storage of refrigerated vaccines.
3. Required temperature range: 2° through 8° C (36° through 46° F).
4. Thermostat setting: Aim average temperature for 5°C (40°F).
5. Maintenance issues: Refer to the equipment owner manual and follow regional guidance on equipment service and replacement.

### **B) Freezers**

1. Health Department Standard: Free-standing freezers designed to maintain proper frozen vaccine storage temperatures at all times.
2. Purpose: Storage of frozen vaccines.
3. Required temperature range -50°C through -15°C (-58°F through 5°F).
4. Thermostat setting: Aim for coldest standard setting (above -50C).
5. Maintenance issues: Refer to the equipment owner manual and follow regional guidance on equipment service and replacement.

### **C) Sensaphone (or equivalent) Alarm System**

1. Health Department Standard: Sensaphones or other alarm systems, although not required, are used in most health departments. The temperature probes should be placed in the center of each refrigerator and freezer unit alongside the digital data logger and should be in a buffered substance.
2. Purpose: To alert staff audibly or by phone 24/7 to improper storage conditions requiring urgent evaluation to prevent vaccine damage.
  - a. Sensaphones do not meet federal requirements for a vaccine thermometer; therefore Sensaphones are for alarm purposes only. All temperature excursions are defined by the certified, calibrated digital data logger and are the basis of all decisions made about vaccine after an excursion. If the Sensaphone triggers an alarm, check the Fridge Tag2 for actual temperatures by downloading the data logger report for review.
3. Recommended Setting (Refrigerator): Set to alarm within 15 minutes of going below 2°C (36°F) and above 8°C (46°F) after 60 minutes. Follow manufacturer instructions on how to set alarm parameters.
4. Recommended Setting (Freezer): Set to alarm after 60 minutes at or above > -15.0°C (5.0°F). To allow for the slight temperature excursions that can happen during the defrost cycle; the alarm should not be set for less than 60 minutes.
5. Notes: Sensaphone alert settings are designed to signal a possible actionable temperature excursion. If set to alarm for non-reportable excursions, staff may be called in at greater frequency and may take action when none is indicated.

## D) Continuous Temperature Monitoring Devices [Fridge Tag2]

1. Health Department Standard: Each storage unit is required to have either a certified, calibrated digital data logger with continuous monitoring and recording capabilities where the data can be routinely downloaded and has the following capabilities:
  - a. An active display that is placed on the outside of the unit door to allow for reading temperatures without opening the unit door.
  - b. A detachable, buffered probe.
  - c. Alarm for out-of-range temperatures.
  - d. Low battery indicator.
  - e. Accuracy of +/- 1°F (0.5°C).
  - f. Memory Storage of at least 4000 readings.
  - g. User programmable logging interval (or reading rate).

Each digital data logger must have a current and valid Certificate of Calibration Testing (or Reports of Calibration Testing). Calibration testing must be performed by a laboratory accredited by an ILAC MRA signatory body or an entity that provides documentation demonstrating the calibration testing performed meets ISO/IEC 17025 International standards for calibration testing and traceability.

2. Purpose: Provides detailed information on all temperatures recorded at preset intervals between fifteen minutes and one hour. Temperatures are considered official and accurate, barring failure of the device. All temperature excursions are defined by the data logger and these are the basis of all decisions made about vaccine after an excursion. A PDF record of the logged temperatures is produced by plugging the device into any USB port on any computer.
3. Settings: The Fridge Tag2 digital data loggers record temperatures every 15 minutes. The alarm triggers have already been preset by the manufacturer. The alarm settings (see below tables) are designed to indicate a too cold refrigerator excursion of 15 consecutive minutes, and a too warm refrigerator excursion of 60 consecutive minutes. The freezer alarms are set to show a too warm excursion of 60 consecutive minutes. These settings cannot be changed in this model. Refer to procedure guidance for definitions of when an excursion is reportable.

Celsius	Duration	Temperature	Alarm Type
<b>Ref.</b>	00:60	8.0	HI
	00:15	2.0	LO
<b>Freezer</b>	00:60	-15.0	HI

Fahrenheit	Duration	Temperature	Alarm Type
<b>Ref.</b>	00:60	46.0	HI
	00:15	35.6	LO
<b>Freezer</b>	00:60	5.0	HI

4. Note: The Fridge Tag2 has a removable wire probe leading to the digital data logger. The wire should enter the unit on the hinge side, high in the corner. Tape the wire in the doorframe with thin clear packing tape to ensure a good seal. Secure the glycol probe in the center of the unit using Velcro to secure to shelving or by placing it in a paper cup.

### **E) Back-up Thermometer**

1. Health Department Standard: Effective January 2015, VFC providers must have at least one backup thermometer with a valid and current certificate of calibration readily available to ensure that temperature assessment and recordings can be performed twice a day.
2. Purpose: Backup thermometers must be readily available in case a thermometer in use is no longer working appropriately or calibration testing of the current equipment is required.
3. Note: Centers for Disease Control and Prevention (CDC) recommends that the backup thermometer be stored outside of the storage unit until needed to avoid vaccine space issues and differing temperature readings leading to potential confusion.

### **F) Portable Powered Back-up Unit**

1. Health Department Standard: Each local health department (LHD) should have access to one in their region.
2. Purpose: Storage of refrigerated or frozen vaccine during transport or off-site clinic.
3. Recommended temperature range:
  - a. For refrigerated vaccine, set to 5°C.
  - b. For frozen vaccines, aim for coldest standard setting (if not <-15°C, then use only if absolutely necessary and keep as cold as possible, recording temperature and time for later consultation with Tennessee Immunization Program Quality Assurance team).
  - c. Follow manufacturer guidance and instruction to ensure the storage unit is set to the correct temperature prior to loading vaccine.
  - d. A certified, calibrated continuous digital data logger must be placed in the unit with the vaccine to provide an official temperature (cannot rely solely on the digital display of the unit).
4. Maintenance issues: Refer to the equipment owner manual and follow regional guidance on equipment service and replacement.
5. Note: Due to the bulk and weight of the portable storage units, it is suggested that practices have a plan for actual transport such as dolly cart and/or have maintenance to help load and unload device.

## Section 2. Temperature Monitoring Procedures

Temperature monitoring is the primary responsibility of the vaccine coordinator and back-up coordinator. Designated staff must review temperatures within each vaccine storage unit two times each day (beginning and end). This review must be documented, as should any actions that are taken if the temperatures readings are out of acceptable range.

The refrigerator should maintain temperatures between 36°F and 46°F (2°C and 8°C). Set the temperature mid-range to achieve an average of 40°F (5°C). The freezer should maintain temperatures between -58°F and +5°F (-50°C and -15°C).

### A) Daily Temperature Monitoring Procedures for Fridge Tag2

#### Morning:

1. When the clinic opens, record the temperature check in each storage unit by pushing the “read” button on the refrigerator and the freezer units three times. Document the time and date of each reading, the initials of person who recorded the reading and whether any new alarms were present on each unit’s Digital Data Logger Sign-off Sheet.
  - a. Note and clear any alarm issues by quickly scanning the lower left hand corner of the device for the X and triangle symbols indicating an alarm has occurred: **Press the “Read” button four times to clear the alarm.** Note: The X symbol may come back in the same day if the problem persists.
    - The first press of the “Read” button the display will show the temperature at the time of the excursion.
    - The second press of the “Read” button will display the date and time of temperature excursion.
    - The third press of the “Read” button will display the duration of the temperature excursion.
    - The fourth press of the “Read” button will clear the alarm.
  - b. If a new alarm is present, refer to the **Temperature Excursion** section (page 8) of this document. If no alarm, proceed with brief visual inspection (correct problems if found):
    - Food and drinks not stored in any refrigerator or freezer used for vaccine storage.
    - Vaccine NOT stored in the doors, drawers, or floor of refrigerator or freezer.
    - Vaccines are stacked with at least one inch of air space between the stacks and two inches between stacks and walls of the unit so air can circulate around the vaccines

- Store bottles of water in the lowest compartment of the refrigerator and in the doors, if space permits, add extra ice packs in the freezer to help maintain temperatures in case of a power outage.
- VFC and 317 vaccines are clearly labeled and separated from privately purchased vaccine for easy identification.

**Afternoon:**

2. An hour before closing, record the temperature check in each storage unit by pushing the “read” button on the refrigerator and the freezer units three times. Document the time and date of each reading, the initials of person who recorded the reading and whether any new alarms were present on each unit’s Digital Data Logger Sign-off Sheet.
  - a. Review and clear any alarm issues by quickly scanning the lower left hand corner of the device for the X and triangle symbols indicating an alarm has occurred: **Press the “Read” button four times to clear the alarm.** Note: The X symbol may come back in the same day if the problem persists.
    - The first press of the “Read” button the display will show the temperature at the time of the excursion.
    - The second press of the “Read” button will display the date and time of temperature excursion.
    - The third press of the “Read” button will display the duration of the temperature excursion.
    - The fourth press of the “Read” button will clear the alarm.
  - b. If a new alarm is present, refer to the **Temperature Excursions** section (page 8) of this document. If no alarm, proceed with brief visual inspection (correct problems if found):
    - Food and drinks not stored in any refrigerator or freezer used for vaccine storage.
    - Vaccine NOT stored in the doors, drawers, or floor of refrigerator or freezer.
    - Vaccines are stacked with at least one inch of air space between the stacks and two inches between stacks and walls of the unit so air can circulate around the vaccines
    - Store bottles of water in the lowest compartment of the refrigerator and in the doors, if space permits, add extra water bottles in the freezer to help maintain temperatures in case of a power outage.
    - VFC and 317 vaccines are clearly labeled and separated from privately purchased vaccine for easy identification.

## **B) Weekly Vaccine Monitoring:**

1. The VFC Contact or their Back-up reviews the Digital Data Logger Sign-off Sheet for each unit to ensure that the unit was checked twice each clinic day and any new alarms were documented.
2. Download the data logger report from the Fridge Tag2 onto a computer (by connecting it to the USB port in any computer) on the same day each week.
  - a. An alarm will occur if the Fridge Tag2 is disconnected from the probe for more than 10 minutes.
3. Print the PDF version of the digital data logger report and sign the comments section to show 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 logger report and whether staff responded appropriately. All information about a TE, including the data logger report and any follow up, should be filed with the temperature logs for the unit and retained for three years.
4. At this time, review your vaccine inventory and ensure vaccines with the shortest expiration dates are in the front to be used first.

## **C) Monthly Vaccine Monitoring**

1. Visually check storage units for correct vaccine and probe placement.
2. Inspect the storage units to ensure cleanliness. Follow the manufacturer's maintenance schedule for the storage unit. Replace the Digital Data Logger Sign-off Sheet for each storage unit. File the completed sheet with the PDF temperature logs for each unit. These documents are required to be maintained for three years.
3. Review vaccine inventory and notify TIP if there is any VFC vaccine with short expiration dates (expiring within 90 days or three months from the current date) that you will not be able to use prior to expiration. Vaccine Inventory Reconciliation is done every month even if vaccine is not ordered.
  - a. For state or locally purchased vaccine that will be expiring within 90 days and it is unlikely will be used before expiration, notify the regional or state pharmacist for the clinic.

## **Section 3. Temperature Excursions (TE)**

### **A) Definitions: Three (3) Levels of Temperature Excursions**

Temperature Excursion: Any time the temperature in a refrigerator unit is outside 2.0°C through 8.0°C (36° through 46°F) or the temperature in a freezer unit is above -15°C (5°F).

1. **Level 1: Non-Reportable Temperature Excursion:** An unavoidable brief time outside the routine recommended ranges that does not necessitate further

inquiry. These are often readily explainable (loading or counting inventory, brief defrost cycle, short power outage or door left ajar).

2. **Level 2: Reportable Temperature Excursion:** A TE that could possibly compromise vaccine and should be reported to the of the Tennessee Immunization Program (TIP) Quality Assurance (QA) Team for further evaluation before any affected vaccine is used. . Vaccine should be quarantined immediately with a “Do Not Use Until Notified by Tip” sign. A reportable TE will not necessarily require calls to manufacturers or action or result in waste of vaccine. However, they do require evaluation by TIP. Sensaphones are designed to alert staff to TEs that meet this level of significance.
3. **Level 3: Actionable Temperature Excursion:** TE that require actions, including waste of certain affected vaccines, transfer of vaccines, replacement or repair of storage unit. Not all reportable TEs end up requiring action.

## B) Reportable Temperature Excursion Procedures

1. Is this a **reportable** temperature excursion? Yes, if it meets any one of the five criteria below:
  - a. Refrigerator temperature dipped below 2.0°C (36°F) for 15 consecutive minutes (or longer).
    - Freezing temperatures below 0°C (32°F) quickly damages vaccine and quick intervention may be necessary to save vaccine if temperature begins to get too cold.
  - b. Refrigerator was above 8.0°C (46°F) for at least 60 consecutive minutes.
  - c. Freezer temperature above -15°C (5°F) for more than 60 consecutive minutes.
    - Routine defrost cycles may go above -15°C (5°F) for less than 60 minutes. There is vaccine stability data to support these types of excursions.
  - d. TE is part of a pattern of frequent excursions, regardless of duration.
  - e. You are concerned about TE even though it doesn't meet above criteria.
2. Reporting Temperature Excursions During Business Hours: Monday – Friday (8:00AM – 4:30PM Central Time):
  - a. If TE is still occurring (temperatures are currently out of range) take the following steps to restore proper storage conditions.
    - Quarantine vaccine; label “Do Not Use until Notified by TIP”.

- Immediately call TIP 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 in TIP.
  - Check to see if the storage unit is unplugged
  - Check to see if the storage unit door is open and is sealed adequately
  - Check the thermostat setting
  - Check location of the probe; should be in the middle of the unit with the vaccine
  - Check the coils and vents for dust
  - If instructed by TIP, follow your Emergency Storage and Handling Plan posted on or beside the storage unit. If storage unit cannot be used, transfer vaccine to the designated back up location.
  - Download temperature log from digital data logger or document current temperature reading on temperature log
  - Note how long the temperature was out of range
  - Note the minimum and maximum temperatures
  - Fax data logger report or temperature log to 615-401-6829
  - If manufacturers must be contacted, you will need to provide an inventory list for any state or local purchased vaccine. Fax the State Vaccine and Medication Temperature Excursion Inventory List to 615-401-6829. TIP will pull an inventory list from TennISS for your VFC and 317 vaccines.
  - The regional or state pharmacist is responsible for follow-up on any non-vaccine items (such as medications or Tubersol) involved in the temperature excursion.
- b. If temperature is currently in range complete the following steps:
- Quarantine vaccine; label "Do Not Use until Notified by TIP".
  - Immediately call TIP 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 in TIP.
  - Download temperature log from digital data logger or document current temperature reading on temperature log
  - Note how long the temperature was out of range

- Note the maximum and minimum temperatures
  - Fax data logger report or temperature log to 615-401-6829
  - If manufacturers must be contacted, you will need to provide an inventory list for any state or local purchased vaccine. Fax the State Vaccine and Medication Temperature Excursion Inventory List to 615-401-6829. TIP will pull an inventory list from TennISS for your VFC and 317 vaccines.
  - The regional or state pharmacist is responsible for follow-up on any non-vaccine items (such as medications or Tubersol) involved in the temperature excursion.
- c. If experiencing a power outage, contact utility company. If restoration is expected within four hours, **do not move vaccine**. Keep the door closed and monitor temperature. This brief TE may be less harmful than transporting vaccine. If power outage is going to last more than four hours, follow your Emergency Storage and Handling Plan.
- d. TIP QA team will take necessary information and if needed, follow up with vaccine manufacturers.
- TIP QA team will follow up on each reportable TE by phone with the clinic staff person and possibly with a brief email summary of the event and guidance on standard template that can be filed with the unit temperature logs.
  - If the TE results in transferring vaccine to another location, the clinic staff will follow the steps for packing and monitoring that are detailed in the current Emergency Storage and Handling Plan posted on or near the storage unit.
  - Do not use any vaccine until approved by TIP.
3. Reporting Temperature Excursion After Business Hours:
- a. Quarantine vaccine; label "Do Not Use until Notified by TIP".
  - b. Download data logger report and review. If storage unit is not currently in range, transfer vaccine to the designated back up location listed in your Emergency Storage and Handling Plan.
  - c. Follow the Emergency Storage and Handling Plan posted on or near the unit. Follow directions for evaluating power outage and only move vaccine if indicated. Vaccine is safer if left in place for a short power outage than it is if moved.
  - d. The next business day contact the TIP QA staff to report TE.

- e. If guidance is needed before the next business day contact TIP at 615-741-7247 or 800-404-3006.
  - The on-call senior epidemiologist for CEDEP will be able to provide a basic consultation but will not provide advice on the viability of the vaccine. In emergencies, Dr. Kelly Moore will be contacted for further consultation.

**C) Non-Reportable Temperature Excursion Procedure**

- a. Clear the alarm on the digital data logger
- b. Initial and record time on the Digital Data Logger Sign-off Sheet and indicate “yes” new alarm was noted.
- c. Write “non-reportable” on PDF of data logger report that was reviewed to evaluate alarm
- d. File the data logger report with the other temperature logs for that unit and maintain for three years
- e. No further action necessary

**D) Transport and Monitoring of Vaccine for Off-site Clinics:**

Guidance is outlined on page 60 in the current edition of the CDC Vaccine Storage and Handling Toolkit. The Toolkit is accessible online at:

<http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm>

## Resources and References

1. CDC's Vaccine Storage and Handling Toolkit  
<http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm>
2. Routine Vaccine Management Tool: Health Department  
[http://tn.gov/assets/entities/health/attachments/2016\\_Routine\\_Vaccine\\_ManagementTool\\_Health\\_Department.pdf](http://tn.gov/assets/entities/health/attachments/2016_Routine_Vaccine_ManagementTool_Health_Department.pdf)
3. Fahrenheit (°F) Temperature Log  
[http://www.tn.gov/assets/entities/health/attachments/Fahrenheit\\_Refrigerator\\_Temperature\\_Logs.pdf](http://www.tn.gov/assets/entities/health/attachments/Fahrenheit_Refrigerator_Temperature_Logs.pdf)  
  
[http://www.tn.gov/assets/entities/health/attachments/Fahrenheit\\_Freezer\\_Temperature\\_Logs.pdf](http://www.tn.gov/assets/entities/health/attachments/Fahrenheit_Freezer_Temperature_Logs.pdf)
4. Celsius (°C) Temperature Log  
[http://www.tn.gov/assets/entities/health/attachments/Celsius\\_Refrigerator\\_Temperature\\_Logs.pdf](http://www.tn.gov/assets/entities/health/attachments/Celsius_Refrigerator_Temperature_Logs.pdf)  
  
[http://www.tn.gov/assets/entities/health/attachments/Celsius\\_Freezer\\_Temperature\\_Logs.pdf](http://www.tn.gov/assets/entities/health/attachments/Celsius_Freezer_Temperature_Logs.pdf)
5. Packing Vaccines for Transport during Emergencies  
<http://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf>
6. Job Aid for Transporting Refrigerated Vaccines  
<http://eziz.org/assets/docs/IMM-983.pdf>
7. Job Aid for Transporting Frozen Vaccines  
<http://eziz.org/assets/docs/IMM-1130.pdf>

## Vaccine Storage Unit Digital Data Logger Sign-off Sheet

Vaccine storage temperatures must be checked twice each day when the clinic is open. After checking, note the time and your name/initials below, and check if a new alarm signal was present. Follow appropriate procedures to evaluate whether a new alarm signal was present. Follow appropriate procedures to evaluate a new alarm and document follow-up on the data logger print out.

Clear the alarm on the data logger.

UNIT (circle): R or F    VFC PIN #: \_\_\_\_\_    UNIT LOCATION: \_\_\_\_\_    MONTH/YR: \_\_\_\_\_

Day of Month	MORNING (AM)				AFTERNOON (PM)			
	Time	Name or initials	New Alarm?  (Circle)		Time	Name or Initials	New Alarm?  (Circle)	
1			Y	N			Y	N
2			Y	N			Y	N
3			Y	N			Y	N
4			Y	N			Y	N
5			Y	N			Y	N
6			Y	N			Y	N
7			Y	N			Y	N
8			Y	N			Y	N
9			Y	N			Y	N
10			Y	N			Y	N
11			Y	N			Y	N
12			Y	N			Y	N
13			Y	N			Y	N
14			Y	N			Y	N
15			Y	N			Y	N
16			Y	N			Y	N
17			Y	N			Y	N
18			Y	N			Y	N
19			Y	N			Y	N
20			Y	N			Y	N
21			Y	N			Y	N
22			Y	N			Y	N
23			Y	N			Y	N
24			Y	N			Y	N
25			Y	N			Y	N
26			Y	N			Y	N
27			Y	N			Y	N
28			Y	N			Y	N
29			Y	N			Y	N
30			Y	N			Y	N
31			Y	N			Y	N

Documentation is required by the federal Vaccines for Children Program. File in paper form or scan and save electronically along with the corresponding month's data logger reports for the unit. Retain for three years.

TN Immunization Program Phone: 800-404-3006 or 615-741-7247



# Temperature Excursion Checklist

For Vaccine Refrigerators and Freezers using a Continuous Temperature Monitor (“data logger”)

**Step 1. Is this a reportable temperature excursion?** Yes, if it meets any one of the 5 criteria below:

- Refrigerator was above 8°C (> 46°F) for 60 consecutive minutes.
- Refrigerator temperature dipped below 2.0°C (<36°F) for 15 consecutive minutes.
- Freezer temperature above -15°C (above 5°F) for 60 consecutive minutes.
- Excursion part of a pattern of frequent excursions, regardless of duration?
- Is this excursion of serious concern even though it does not meet the above criteria?

**If YES to any of the above: Go to reportable temperature excursion procedure below.**

**If NO:** the alarm is insignificant: clear alarm on data logger, note that it is insignificant on data logger printout and file in temperature log. No further action necessary.

**If Reportable Temperature Excursion Response During Business Hours (8AM-4:30 PM Central)**

**Step 2.** Take steps to restore proper storage conditions. Briefly notify appropriate regional office contact of situation and that TIP is being contacted. If considering transferring vaccine, TIP QA staff can be of assistance in making that decision.

- a. Refer to your Routine/Emergency Storage and Handling Plan posted on or beside the unit to review the basic functioning of the unit.
- b. If power out, contact utility company. If restoration expected <4 hours, do not move vaccine.

**Step 3.** Have the following information ready when you call TIP Quality Assurance (QA) Team:

- c. Data Logger Report should be downloaded and ready for review with TIP
- d. The time that the temperature was first noted out of range \_\_\_\_\_
- e. How high or low did the temperature go outside the recommended range? \_\_\_\_\_
- f. The time that vaccines were returned to proper temperatures \_\_\_\_\_
- g. Were any open vials of multi-dose vaccine involved? \_\_\_\_\_
- h. Have the vaccines been involved in any other reportable temperature excursion? \_\_\_\_\_
- i. Is your MMR vaccine kept in the refrigerator or freezer?  Refrigerator  Freezer

**Step 4a.** If freezer is affected, and TIP determines manufacturer must be called, TIP will request varicella doses with LOT number & expiration date at that time.

**Step 4b.** If manufacturers must be called and state vaccine inventory is involved, TIP will request an inventory of the state vaccine (federal vaccine inventory will be accessed online).

*If calls to (800)404-3006 are not answered promptly by a person, call the CEDEP main desk at (615)741-7247 and ask the receptionist to locate someone in TIP immediately. The TIP QA team is responsible for making follow-up arrangements if away from the office.*

# Temperature Excursion Checklist (Back Page)

## After Hours Reportable Temperature Excursion Response

- a) Follow directions of the Routine/Emergency Storage and Handling Plan posted on or near the unit. If this is due to a power outage, evaluate the situation and move vaccine *if indicated*. Vaccine is safer if left in place for a short power outage than it is if moved.
- b) Mark vaccine temporarily “do not use” until TIP QA staff consulted next business morning
- c) If not already contacted, briefly notify appropriate regional office contact of situation and need to contact TIP. Contact TIP QA staff after 8AM on the next business day **before** administering vaccine.
- d) When do I call TIP after hours and what will be done? This is rarely necessary.
  - i) Calling (615)741-7247 will provide directions for calling the on-call senior epidemiologist for CEDEP. This person can provide very basic consultation but will not provide advice about whether vaccine may be used. In emergencies, this person will contact Dr. Kelly Moore for follow-up.

## **Follow up:**

1. Responsible clinic staff person (or designee) is responsible for alerting regional staff of the reportable event and ensuring people in the following roles are copied on emails about the excursion, and to ensure they receive a copy of the final recommendations from TIP:
  - a. Regional Pharmacist
  - b. Regional Nursing Director
  - c. Regional Health Officer
  - d. Regional Immunization Representative

*NOTE: The regional or state Pharmacist is responsible for follow up on any non-vaccine items (such as medications or Tubersol) involved in a temperature excursion.*
2. TIP QA staff will follow up on each reportable temperature excursion by phone with the clinic staff person and with a brief **email** summary of the report and guidance given.
  - a. TIP QA staff will try to copy the above-listed regional staff, but the responsible clinic staff person should confirm that all receive a copy of the email response promptly.
  - b. The report may be shared with other local or regional staff as necessary.
  - c. A copy of the follow up report should be kept with the temperature log records for that unit and maintained for three years.

**Reportable Temperature Excursion: STATE & Non-Federal Vaccine and Refrigerated Medications**

SP= Sanofi Pasteur

Inventory list includes all possible vaccines. In event of a reportable temperature excursion, use this to report inventory of any non-Federal (private, state or local public) vaccine stock to the TN Immunization Program. All non-vaccine inventory should be reported to the pharmacist responsible for the clinic.

<u>Product</u>	<u>Brand Name</u>	<u># of Doses</u>	<u>Lot Number</u>	<u>Exp.</u>	<u>Action Plan</u>	<u>Action Completed Date/Initial</u>
<b>DTaP</b>	Daptacel					
	Infanrix					
<b>DT</b>	Generic (SP)					
<b>DTaP-IPV</b>	Kinrix					
<b>DTaP-HepB-IPV</b>	Pediarix					
<b>DTaP-IPV-Hib</b>	Pentacel					
<b>Hib</b>	PedvaxHIB					
	ActHIB					
	Hiberix					
<b>HepA</b>	Havrix *Please indicate adult or ped					
	Vaqta *Please indicate adult or ped					

Date of Excursion:

Inventory Completed by:

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**Reportable Temperature Excursion: STATE & Non-Federal Vaccine**

SP= Sanofi Pasteur Inventory list includes all possible vaccines. In event of a reportable temperature excursion, use this to report inventory of any non-Federal (private, state or local public) vaccine stock to the TN Immunization Program. All non-vaccine inventory should be reported to the pharmacist responsible for the clinic.

<u>Product</u>	<u>Brand Name</u>	<u># of Doses</u>	<u>Lot Number</u>	<u>Exp.</u>	<u>Action Plan</u>	<u>Action Completed Date/Initial</u>
<b>HepB</b>	Engerix-B *Please indicate adult or ped					
	Recombivax HB *Please indicate adult or ped					
<b>HepA-HepB</b>	Twinrix					
<b>Herpes Zoster</b>	Zostavax					
<b>HPV</b>	Gardasil Quad					
	Gardasil 9					
	Ceravix					
<b>Influenza</b>	Fluarix					
	Fluvirin					
	Fluzone					
	FluMist					
	FluLaval					
	Afluria					
	Agriflu					
<b>Jap. Encephalitis</b>	Ixiaro					
<b>MMR</b>	M-M-R II					

**Reportable Temperature Excursion: STATE & Non-Federal Vaccine**

SP= Sanofi Pasteur Inventory list includes all possible vaccines. In event of a reportable temperature excursion, use this to report inventory of any non-Federal (private, state or local public) vaccine stock to the TN Immunization Program. All non-vaccine inventories should be reported to the pharmacist responsible for the clinic.

<b><u>Product</u></b>	<b><u>Brand Name</u></b>	<b><u># of Doses</u></b>	<b><u>Lot Number</u></b>	<b><u>Exp.</u></b>	<b><u>Action Plan</u></b>	<b><u>Action Completed Date/Initial</u></b>
<b><u>Meningococcal MCV4</u></b>	Menactra					
	Menveo					
<b><u>Pneumococcal</u></b>	Pneumovax 23					
	Prevnar 13					
<b><u>Polio</u></b>	Ipol					
<b><u>Rabies</u></b>	Imovax Rabies					
	RabAvert					
<b><u>Rotavirus</u></b>	Rota Teq					
	Rotarix					
<b><u>Tetanus-Diphtheria</u></b>	Tenivac					
	Generic (Mass. Biological)					
<b><u>Tdap</u></b>	Boostrix					
	Adacel					
<b><u>Typhoid</u></b>	Typhim Vi					
	Vivotif Berna					





## Reportable Vaccine Storage Temperature Excursion Summary

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

Time: \_\_\_\_:\_\_\_\_ am pm

Name of Clinic: \_\_\_\_\_ VFC PIN#: \_\_\_\_\_

Name of Caller: \_\_\_\_\_

Phone: (\_\_\_\_)\_\_\_\_-\_\_\_\_ Contact Email: \_\_\_\_\_

Date of Initial Call: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time of Initial Call: \_\_\_\_:\_\_\_\_ am pm

Description of Event:

Recommended Actions:

Mark Date of Vaccines with Date of Excursion: yes no

Wasted Vaccine:

TIP Quality Assurance Team Member Completing Report: \_\_\_\_\_

Distribution Instructions: Public Health Clinics

- Copies should be sent to the following: TIP Program Manager, TIP Director, TIP QA Team, clinic point of contact, key regional or metro staff
- The clinic point of contact should verify that a copy is received by all appropriate regional or metro staff, to include: Pharmacists responsible for clinic, Nursing Director, Health Officer and Immunization Representative
- Retain this record on file with temperature logs from the corresponding dates. Records are required to be kept for three years. For additional questions email or call (800)404-3006.