

Tennessee Department of Health

**Vaccine temperature monitoring
guidance for all federal, state or local
vaccines stored in public health clinics**

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Related Forms and Resources

1. *Digital Data Logger Sign-off Sheet*
2. *Temperature Excursion Checklist*
3. *CDC Vaccine Storage and Handling Toolkit Vaccine Transport Chapter (May 2014)*
4. State vaccine and medication inventory record
5. Sample of TIP reportable excursion response template
6. Vaccine Transport Resources
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 - b. Job Aid for Packing Refrigerated Vaccine for Transport (EZIZ-California)
 - c. Job Aid for Packing Frozen Vaccine for Transport (EZIZ-California)

Section 1. Vaccine Storage/Monitoring Equipment Purpose and Settings

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. Recommended temperature range: 2° through 8° C (35° 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. Recommended temperature range -50°C through -15°C (-58°F through +5°F)
4. Thermostat setting: Aim for coldest standard setting (above -50C)
5. Notes: Temperatures below -50°C (-58°F) are to be avoided because they may affect the seal of the natural latex stopper and could theoretically risk contamination (the vaccine would still work).
6. 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. For simplicity, this document refers to such systems simply as “Sensaphones”. Temperature probes are in glycol or glass beads and placed in the center of each refrigerator and freezer unit alongside the digital data logger.
2. Purpose: To alert staff audibly or by phone 24/7 to improper storage conditions requiring urgent evaluation to prevent vaccine damage.
 - (1) **Not intended to alarm for insignificant excursions.** Alerts to possible impending freeze damage (0°C, 0°F or colder) is most urgent.
 - (2) Sensaphones do not meet federal requirements for a vaccine thermometer, therefore Sensaphones are for alarm purposes only **After a Sensaphone alarm, the certified, calibrated digital data logger record is the basis for all further decisions.**

3. Setting (Refrigerator): Sensaphones with a single probe should alarm **within 15 minutes of going below 2°C (or 35°F)**. Upper temperature alarms should call out at **above 15.0°C (above 59°F) after 15 minutes**. Follow manufacturer instructions on how to set alarm parameters.
 - (1) If a second probe is being used in the unit, it may be used to set the upper limits to alarm at a different period of time out of range than the lower limit. If such a second probe is used, it should be set to alarm above 9.0°C (above 48°F) for 60 minutes, which is the definition of a warm refrigerator reportable temperature excursion.
4. Setting (Freezer): **Set to alarm after 1 hour at or above -12.0°C or 8.0°F**. The alarm should not be set for less than 60 minutes because slight warm temperature excursions under 1 hour can be a normal part of a defrost cycle; frozen vaccine is designed to tolerate this. There is no need for a too-cold alarm in the freezer.
5. Notes: Sensaphone alert settings are designed to signal "reportable" possibly actionable temperature excursions. If set to alarm for insignificant excursions, staff may be called in at greater frequency and may take action when none is indicated.

D) Continuous Temperature Monitoring Devices [Digital Data Loggers, Fridge Tag 2]

1. Health Department Standard: Certified, calibrated digital data loggers for continuous monitoring of the temperatures in each vaccine storage unit. Each unit has a current certificate of calibration and traceability and requires replacement or recalibration every 24 months or when the manufacturer certificate of calibration expires, if sooner. Data loggers meet all required and recommended specifications published by the Centers for Disease Control and Prevention (CDC).
2. Purpose: Provides detailed information on all temperatures recorded at preset intervals between 15 minutes and 1 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: Digital data loggers purchased in October of 2013 record temperatures every 15 minutes. The alarm triggers were preset by the manufacturer. The alarm settings (see below) are designed to indicate ALL excursions of 15 minutes or longer that hit or exceed the threshold of the FDA recommended temperature ranges (see table below), including insignificant excursions that are not reportable. These settings cannot be changed in this model. Refer to procedure guidance for definitions of when an excursion is reportable.

Celsius Alarm	Duration	Temperature	Alarm Type
Ref.	00:15	8.0	HI
	00:15	2.0	LO
Freezer	00:15	-15.0	HI
	23:59	-30.0	LO

Fahrenheit Alarm	Duration	Temperature	Alarm Type
Ref.	00:15	46.0	HI
	00:15	35.0	LO
Freezer	00:15	5.0	HI
	23:59	-22.0	LO

Note: The data loggers in LHDs have a removable wire probe leading to the device. It 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, the CDC requires each clinic storing federal vaccine to maintain a back-up certified, calibrated thermometer, stored outside of any storage unit. The thermometer is required to have appropriate current certificate of calibration and traceability that does not expire at the same time as the digital data logger.
2. Purpose: The back-up thermometer should be available in case the thermometer in use is no longer working appropriately or if needed for vaccine transport or other reason.
3. Note: CDC recommends that the back-up thermometer be stored outside the storage unit until needed to avoid the inevitably slightly different temperature readings in the storage unit leading to confusion.

F) Portable Powered back-up Unit

1. Health Department Standard: One in each LHD, most purchased in 2009
2. Purpose: Storage of refrigerated or frozen vaccine during transport or off-site clinic
3. Recommended temperature range: same as normal refrigerator, freezer.
4. Thermostat setting:
 - (1) For refrigerated vaccine, set to 5°C.
 - (2) For frozen, aim for coldest standard setting (if not $\leq -15^{\circ}\text{C}$, then use only if absolutely necessary and keep as cold as possible, recording temperature and time for later consultation with TIP QA team).
5. Notes:
 - (1) These units are heavy and bulky. Plan in advance for adequate staff or equipment to load and transport them.

- (2) Follow manufacturer guidance and instruction to ensure that storage unit is set to the correct temperature prior to loading vaccine.
 - (3) A certified, calibrated thermometer 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) 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 maintenance to help load and unload device.
6. Maintenance issues: Refer to the equipment owner manual and follow regional guidance on equipment service and replacement

2) Section 2: Temperature Monitoring Procedures

- A. **Definitions:** 3 Levels of Temperature Excursions (“TEs”)
- a. **Temperature Excursion (generic):** Any time the temperature in a storage unit is outside 2.0°C through 8.0°C (35° through 46°F) or the temperature in a freezer is above -15°C (5°F). Digital data loggers will display an alarm at *any* TE lasting 15 minutes or more, including insignificant TEs that are part of normal activity and do not require reporting or action.
 - b. **Level 1: Insignificant Temperature Excursion:** An unavoidable brief time <60 minutes outside the routine recommended ranges that does not necessitate further inquiry. See specific definition in the first step of the TE response procedure. These are often readily explainable (loading or counting inventory, brief defrost cycle, short power outage or door left ajar). Digital data loggers that record every 15 minutes frequently detect and alarm to these, a feature that cannot be fixed at this time.
 - c. **Level 2: Reportable Temperature Excursion:** A TE that could possibly compromise vaccine and should be reported to the Quality Assurance (QA) Team of the Tennessee Immunization Program (TIP) for further evaluation before any affected vaccine is used, as described in the reportable TE protocol below. 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.
 - i. **Level 3: Actionable Temperature Excursion:** A subset of reportable TEs that require action, including waste of certain affected vaccines, transfer of vaccines, or replacement or repair of storage unit. Not all reportable TEs end up requiring action.

Resources and references:

CDC Vaccine Storage and Handling website (All of the current guidelines, resources, including the online Vaccine Storage and Handling Toolkit): <http://www.cdc.gov/VACCINES/RECS/storage/default.htm>

TN Immunization Registry (TWIS) website, currently: <http://twis.tn.gov>

Click on VFC Program Forms to access data logger guidance, job aids for setting up storage units, and other references. In late 2014, transition to the new TennIIS system will be complete.

To reach TIP, call CEDEP at (615)741-7247 or call (800)404-3006.

B. Data Logger Routine Temperature Monitoring Procedure

a. Daily Monitoring:

Morning:

- 1) When clinic opens, record the temperature check in each storage unit by pushing the “read” button on the refrigerator and the freezer units. Note time/initials 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 top edge of the device for symbols indicating a date and time of an alarm: 
 - b) If a **new alarm** is present, **proceed to the temperature excursion (TE) protocol of this document (page 10) or the one-page TE checklist**. If not, proceed with brief visual inspection (correct problems if found):
 - i) Food and drinks **not** stored in any refrigerator or freezer used for vaccine storage.
 - ii) Vaccine NOT stored in the doors, drawers, or floor of refrigerator or freezer.
 - iii) Vaccines are stacked with at least one (1) inch of air space between the stacks and two (2) inches between stacks and walls of the unit so air can circulate around the vaccines
 - iv) 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.
 - v) VFC/317/other vaccines are clearly labeled and separated from privately purchased vaccine for easy identification.

Afternoon:

- 2) Within about an hour of closing, record the temperature check in each storage unit by pushing the “read” button on the refrigerator and the freezer units. Note time/initials and whether any new alarms were present on each unit’s sign sheet.
 - a) Note and clear any alarm issues by quickly scanning the top edge of the device for symbols indicating a date and time of an alarm
 - b) If a **new alarm** is present, **proceed to the temperature excursion (TE) protocol of this document (page 10) or the one-page TE checklist**:
 - i) Food and drinks **not** stored in any refrigerator or freezer used for vaccine storage.
 - ii) Vaccine NOT stored in the doors, drawers, or floor of refrigerator or freezer.
 - iii) 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
 - iv) 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.
 - v) VFC/317/other vaccines are clearly labeled and separated from privately purchased vaccine for easy identification.

b. **Weekly Routine Vaccine Monitoring:**

- 1) A supervisor or designee confirms that the digital data logger sign off sheet for the unit indicates that the unit was checked AM and PM each clinic day and any new alerts were noted.
- 2) Download a report from the device onto a computer (by connecting it to the USB port in any computer) on the same day each week.
 - a) Remember: the device will alarm if it is disconnected for more than 10 minutes.
 - b) Note any alarms on the logger report and whether staff responded appropriately, either by indicating the TE was insignificant or by reporting and acting as directed in the TE protocol. 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 3 years, along with those logs.
 - c) Print the download 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.
 - d) Contact TIP Quality Assurance team for any questions.
- 3) Review vaccine inventory. Rotate so vaccines with the shortest expiration dates are used first.

c. **Monthly Routine Vaccine Monitoring:**

- 1) Visually check storage units for correct placement, and check for cleaning and proper function.
- 2) Replace the digital data logger sign off sheet for each storage unit. File the complete sheet with the PDF temperature logs for that unit. These must be maintained for 3 years.
- 3) Inventory: Notify the TIP VFC Operations Unit of VFC vaccine with short expiration dates (expiring within 90 days or 3 months from the current date) if the vaccine is unlikely to be used before it expires. Users of the online Vaccine Inventory Management (VIM) system (or *TennIIS* equivalent) adjust their inventory in that system: VFC Operations will be notified by the system.

- 4) For state or locally-purchased vaccine within 90 days of expiration and unlikely to be used before expiration, notify the regional or state pharmacist for the clinic.

C. Procedures for Temperature Excursions

Note: If the TE alert was initially signaled by a *Sensaphone alarm*, staff must **check the digital data logger for the actual temperature record**. Download a report from the data logger to review. All protocols are based upon data from the digital data logger.

Sensaphones are only used to alert staff to the *possibility* of a reportable TE for further evaluation using the data logger.

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

- (1) Data logger indicates refrigerator temperature dipped **below 2.0°C (35.0°F) for at least 15 minutes.**

- (a) *Why so short? Freezing temperatures below 0°C quickly damage vaccine, and quick intervention may be necessary to save vaccine if temperature begins to get too cold*

- (2) Data logger indicates refrigerator was **above 9.0°C (48°F) for at least 60 minutes**

- (3) Data logger indicates freezer temperature **above -15.0°C (5°F) for more than 60 minutes.**

- (a) *Why longer? Because routine defrost cycles may go above -15°C for less than 60 minutes and the vaccine is designed to tolerate that*

- (4) Is this TE part of a pattern of frequent excursions, regardless of duration?

- (5) Is this TE worrisome for some other reason even though it does not meet the above criteria?

- **If YES to any of the above: Go to reportable TE procedure below.**

- **If NO:** the alarm is insignificant:

1. Clear alarm on data logger

2. Initial Digital Data Logger Sign Off Sheet and indicate “yes” new alarm was noted.

3. Write “insignificant” on PDF of data logger report that was reviewed to evaluate alarm

4. File this log with the other temperature logs for that unit and keep for 3 years

5. No further action necessary

b. Reportable Temperature Excursion Response During Business Hours (8AM-4:30PM

Central) 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 they are not at their desks; follow prompts on their voicemail message for instructions.

1. If TE situation is *ongoing* (vaccine temperatures are currently out of range)
 - a. Take steps to restore proper storage conditions. After a brief notification of the appropriate regional health office contact, call the TIP QA Team for immediate assistance, especially if considering relocating vaccine but unsure.
 - i. Refer to your Routine/Emergency Storage and Handling Plan posted on or beside the unit. Is unit plugged in? Is door closed and sealed adequately? Is unit maintained properly (thermostat setting correct, coils cleaned)?
 - ii. If power out, contact utility company. Determine if time to restoration is acceptable. If restoration expected within 4 hours, do not move vaccine. Keep door closed and monitor. This brief TE may be less harmful than transporting the vaccine.
 - b. Temporarily label vaccines (or unit door) "Do Not Use". Do not administer vaccine until approved by TIP.
2. If the situation is **not** ongoing (vaccine is currently at proper temperatures), proceed to next step:
 - a. Download data from digital data logger to review
 - b. Note how long the temperature was out of range
 - c. Note the maximum temperature or minimum temperatures reached
3. Responsible clinic staff person then briefly alerts the appropriate regional health department contact of the situation, and then calls the TIP QA Team directly to report.
 - a. *Why start with a phone call? The best guidance can be provided when TIP QA team can discuss follow up questions about the unit or the situation from those directly involved.*
 - b. If the TE involves a storage unit, the TIP QA staff member will normally request an emailed copy of the data logger report; please ensure to copy the appropriate regional staff on emails:
 - Regional Pharmacist
 - Regional Nursing Director
 - Regional Health Officer
 - Regional Immunization Representative
 - Other (if directed locally)
 - *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.*
4. TIP QA staff will take necessary information and follow up with vaccine manufacturers, if needed
 - a. TIP will access inventory of federal vaccine (VFC and 317) online, if needed
 - b. If manufacturers must be contacted concerning non-Federal (state or local) vaccine, the responsible clinic staff person will be asked to provide the

inventory (not accessible online to TIP staff). Please use the state vaccine and medication temperature excursion inventory list for this purpose.

- c. **TIP staff need to know** if there are any *open* multidose vials, whether MMR vaccine is stored in the refrigerator or the freezer, and the lot numbers of varicella vaccine (if involved).
5. TIP QA staff will follow up on each **reportable** TE by phone with the clinic staff person and with a brief **email** summary of the event and guidance on standard template that can be filed with the unit temperature logs. This will include whether the staff should indicate the date of the temperature excursion on the packages of affected vaccines for future reference.
 - a. TIP QA staff will copy as many of the above-listed regional staff in step 4, but the responsible clinic staff person should review the email to verify that all regional or local staff who need it receive a copy of the email response.
 - b. The report may be shared by recipients with other local or regional staff as necessary.
 - c. A copy should be kept with the temperature records for that unit and maintained for 3 years.
 6. 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 Routine and Emergency Vaccine storage plans posted on or near the storage units.

C. Reportable Temperature Excursion Response: After Business Hours (weekends, holidays or after business hours in Nashville)

1. Follow directions of the Routine/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.
2. Download data logger report and review. If storage unit cannot be used, transfer vaccine to the designated back up location.
3. Contact TIP QA staff after 8AM on the next business day and **before** administering affected vaccine to any patient.
4. In the event that you are unable to properly execute the emergency storage and handling plan or restore vaccine to in range temperature; clearly mark the vaccine "Do Not Use" and contact TIP immediately the next business day. For example: a storm or other hazard may make it unsafe for staff to attempt to go to the health department or to move vaccine to a different location.
5. 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.

D. Transport and monitoring of vaccine for off-site clinics:

Guidance is outlined 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>

Transport guidance is located on pages **69-72** of the PDF document and a copy should be filed with this protocol. In addition, job aids from California's EZIZ website are included which contain additional details for packing refrigerated or frozen vaccine for transport. Details of packing also are included in the Routine and Emergency Vaccine Storage Plan located on or near the storage unit.

Contact the TIP QA team with any questions.

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 whether a new alarm  signal was present. Follow appropriate procedures to evaluate a new alarm and document follow-up on data logger print out.

Unit (circle): R or F **VFC PIN#:** _____ **Location of Unit:** _____ **Month/Yr:** _____

Day of Month	Morning (AM)			Afternoon (PM)		
	Time	Name or Initials	New Alarm? 	Time	Name or Initials	New Alarm? 
1			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
2			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
3			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
4			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
5			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
6			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
7			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
8			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
9			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
10			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
11			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
12			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
13			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
14			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
15			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
16			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
17			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
18			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
19			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
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23			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
24			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
25			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
26			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
27			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
28			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
29			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
30			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No
31			<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No

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 3 years.

Last updated by TN Immunization Program, July 2014. Phone: (800)404-3006 or (615)741-7247.

Vaccine Storage Unit Digital Data Logger Sign-off Sheet (Back Page)

If a new alarm is noted on the front page, please indicate category below:

Month/ Year _____

New Alarm Day (AM or PM)		Category	
Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable
Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable
Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable
Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable
Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable
Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable
Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable
Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable
Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable
Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable
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Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable
Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable
Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable
Day: _____	<input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> Insignificant	<input type="checkbox"/> Reportable

The first time a new alarm is noted, download data logger report to evaluate the temperature excursion (TE).

- A. If the TE is **insignificant** under the definition in the current protocol, indicate “insignificant” on the data logger report and place in the temperature monitoring file for the storage unit.
- B. If the TE is **“reportable”** to the TN Immunization Program under the definition in the current protocol, follow reporting procedures and document your actions on the data logger report.

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 9°C (> 47°F) for at least 60 minutes.
- Refrigerator temperature dipped below 2.0°C (<35°F) for at least 15 minutes.
- Freezer temperature above -15°C (above 5°F) for more than 60 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 multidose 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?

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 3 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>
DTaP	Daptacel					
	Infanrix					
DT	Generic (SP)					
DTaP-IPV	Kinrix					
DTaP-HepB-IPV	Pediarix					
DTaP-IPV-Hib	Pentacel					
Hib	PedvaxHIB					
	ActHIB					
	Hiberix					
HepA	Havrix *Please indicate adult or ped					
	Vaqta *Please indicate adult or ped					

<u>Date of Excursion:</u>	<u>Inventory Completed by:</u>
---------------------------	--------------------------------

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.

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

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>
Meningococcal MCV4	Menactra					
	Menveo					
Pneumococcal	Pneumovax 23					
	Prevnar 13					
Polio	Ipol					
Rabies	Imovax Rabies					
	RabAvert					
Rotavirus	Rota Teq					
	Rotarix					
Tetanus-Diphtheria	Tenivac					
	Generic (Mass. Biological)					
Tdap	Boostrix					
	Adacel					
Typhoid	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:

Description of any recommended actions:

Should date of excursion be noted on affected vaccine packages? Yes No
If any vaccine is recommended to be wasted, note here:

TIP Quality Assurance Team Member completing this 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: Pharmacist responsible for clinic, Nursing Director, Health Officer, and Immunization Representative
- Retain this record on file with temperature logs from the corresponding time. Records are required to be retained for 3 years. For additional questions, email or call (800)404-3006.



Key Messages:

-  If at all possible, have vaccines delivered directly to an off-site/satellite facility.
-  If vaccines must be transported to off-site/ satellite facility, the amount transported should be limited to only what is needed for that workday. Transport and workday should total no more than a maximum of 8 hours.
-  Use a calibrated temperature monitoring device with continuous monitoring and recording capabilities during transport.
-  CDC recommends transport of refrigerated or frozen vaccines using a portable refrigerator/ freezer unit.
-  If necessary, varicella-containing vaccines that have not been reconstituted may be transported at refrigerated temperatures. However, you must contact the **vaccine manufacturer** for guidance upon arrival at off-site/satellite facility.
-  When packing vaccines for transport, use a barrier layer between coolant packs and vaccines and place a calibrated temperature monitoring device next to vaccines.
-  Do NOT use dry ice to transport varicella-containing vaccines.
-  Diluents should be transported with corresponding vaccines at storage temperatures specified in **package insert** .
-  In advance, refrigerate diluents stored at room temperature before transporting in same container with refrigerated vaccines so they will not increase temperature in container.
-  NEVER freeze diluents, even in transport.
-  Read and record storage unit temperature at off-site/satellite facility a minimum of 2 times during the workday.
-  If vaccines are kept in transport container, read and record temperatures hourly.

Emergency or Off-site/Satellite Facility Transport

-  If you provide VFC vaccines or other vaccines purchased with public funds, contact your **immunization program**  regarding vaccine transport, details on how to pack vaccine and diluent, and procedures for maintaining the cold chain.

General Recommendations

Transport involves the movement of vaccine over a short time and distance between providers. Vaccine manufacturers do not generally recommend or provide guidance for transport of vaccines and CDC discourages routine transport.

-  If at all possible, have vaccines delivered directly to an off-site/satellite facility. Each



transport increases risk of exposing vaccines to inappropriate storage conditions.

If vaccines must be transported to off-site/satellite facility, the amount transported should be limited to only what is needed for that workday. Transport and workday should total no more than a maximum of 8 hours.



CDC recommends using a calibrated temperature monitoring device with continuous monitoring and recording capabilities during transport.

CDC does NOT recommend using cold chain monitors (CCMs in [Unpacking Deliveries](#)) during transport since they do not provide adequate data on excursions that may occur. Providers should contact [immunization program](#) and/or [vaccine manufacturer\(s\)](#) for guidance.



The facility SOP should specify that vaccines are:

- Monitored with calibrated temperature monitoring device
- Not placed in vehicle trunk
- Delivered directly to facility
- Promptly unpacked and placed into appropriate storage units upon arrival ([Unpacking Deliveries](#))



When transporting vaccines in non-commercial vehicles use the passenger compartment—not the trunk.

There are many variables to consider when transporting vaccines:

- Type of vaccines
- Time of year and seasonal temperature
- Amount of vaccines
- Container, packing materials, pack out method
- Number of times container is opened and closed

Contact your [immunization program](#) for specific guidance regarding vaccine transport, details on how to pack vaccine and diluent, and procedures for maintaining cold chain.

General Guidance

Refrigerated vaccines

- Pack refrigerated vaccines before packing frozen vaccines.
- CDC recommends transport with a portable refrigerator unit. If this type of unit is not available, a hard-sided insulated cooler with at least 2-inch walls may be used if it can maintain recommended temperature range (between 35°F and 46°F [2°C and 8°C]).
- Place a layer (at least 2 inches) of “conditioned” coolant packs in transport container first. Coolant packs that are frozen must be “conditioned” by leaving them at room temperature for 1 to 2 hours until edges have defrosted and packs look like they’ve been “sweating.” Frozen coolant packs that are not “conditioned” can freeze vaccines.
- Place an insulating barrier layer on top of coolant packs (e.g., bubble wrap or Styrofoam pellets).
- Next, place a calibrated temperature monitoring device (preferably with a probe



in a thermal buffer, e.g., glycol) on top of barrier.

- Next, stack vaccines with temperature monitoring device on top of barrier.
- Place another insulating barrier layer on top of vaccines.
- Place another layer of “conditioned” coolant packs on top of barrier.
- Always ensure there is no direct contact between coolant packs and vaccines.
- Place a final insulating barrier layer (at least 2 inches) on top of coolant packs along with a list of vaccines in container.

Transporting Varicella-containing Vaccines

The vaccine manufacturer does not recommend transporting varicella-containing vaccines (VAR, HZV, MMRV).

If these vaccines must be transported (e.g., during an emergency):

-  CDC recommends transport in a portable freezer unit that maintains temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent in some places.
- If not using a portable freezer, use same packing layers as noted above.
- Coolant packs should be frozen.

If necessary, varicella-containing vaccines that have not been reconstituted may be transported at refrigerator temperature between 36°F and 46°F (2°C and 8°C) for up to 72 continuous hours prior to reconstitution ([package inserts](#) ).

Follow these steps:

1. Place a calibrated temperature monitoring device (preferably with a probe in a thermal buffer, e.g., glycol) in the container as close as possible to vaccines.

If transported in same container with refrigerated vaccines, place insulating material (e.g., bubble wrap) around refrigerated vaccines to protect from freezing temperatures and use rubber bands around frozen vaccines to keep them separate.

2. Record:
 - a. Time vaccines are removed from storage unit and placed in container
 - b. Temperature during transport
 - c. Time at end of transport when vaccine returned to main storage unit
3.  Immediately upon arrival at off-site/satellite facility:
 - a. Place varicella-containing vaccines in freezer between -58°F and +5°F (-50°C and -15°C) and label “Do NOT Use.” Any stand-alone freezer that reliably maintains a temperature between -58°F and +5°F (-50°C and -15°C) is acceptable for storage of varicella-containing vaccines.
 - b. Document time vaccines are removed from container and placed in alternate storage unit.
 - c. Note: This is considered a temperature excursion. Do NOT use vaccine until the vaccine manufacturer is contacted at 1-800-637-2590 for guidance.
4. Do not discard vaccines without contacting your [immunization program](#)  and/or [vaccine manufacturer\(s\)](#) for guidance.

Do NOT use dry ice, even for temporary storage or emergency transport. Dry ice may expose varicella-containing vaccines to temperatures colder than -58°F (-50°C).



Diluents



Diluents should be transported with their corresponding vaccines to ensure there are always equal amounts of vaccine and diluent for reconstitution. Follow manufacturer guidance for specific temperature requirements. Diluents that contain antigen (e.g., DTaP-IPV diluent used with Hib lyophilized vaccine) should be transported with corresponding vaccines at refrigerator temperature. Place an insulating barrier between diluents and coolant packs.

Refrigerate, in advance, diluents stored at room temperature before transporting in same container with refrigerated vaccines so they will not increase temperature in container.

NEVER freeze diluents, even in transport.

Multidose Vials

Only if absolutely necessary, a partially used vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained. However, a partially used vial may NOT be transferred to another provider or transported across state lines.

Monitoring Temperatures at Off-site/Satellite Facility



Immediately upon arrival at off-site/satellite facility, store vaccines at recommended temperature range in an on-site refrigerator or freezer. Place a calibrated temperature monitoring device(s) in storage unit(s) with vaccines.



Read and record temperatures a minimum of 2 times during the workday if the vaccines are stored in a refrigerator and freezer.

CDC does not recommend keeping vaccines in a transport container(s) unless it is a portable refrigerator or freezer unit. If vaccines must be kept in a transport container(s) during an off-site clinic, temperature(s) should be read and recorded at least hourly. In addition:

- Container(s) should remain closed as much as possible
- A calibrated temperature monitoring device(s) (preferably with a probe in a thermal buffer, e.g., glycol) should be placed as close as possible to vaccines
- Only amount of vaccine needed at one time (no more than 1 multidose vial or 10 doses) should be removed for preparation and administration by each vaccinator



If you have concerns about vaccines or diluents that may have been compromised (exposed to inappropriate conditions/temperatures or handled improperly), label them "Do NOT Use" and store them under appropriate conditions (set apart from other vaccines).



Immediately contact your [immunization program](#) and/or [vaccine manufacturer\(s\)](#) for guidance. Do NOT discard the vaccines or diluents unless directed to by your immunization program and/or manufacturer(s).

Transporting Refrigerated Vaccine

Guidelines for vaccine transport and short-term storage

- The procedure below for packing vaccine will keep all vaccines (**except varicella vaccine**) within recommended temperatures for 12 hours during transport and/or storage at room temperatures (inside a car, building, etc.). It will also maintain recommended temperatures if the cooler is exposed to outside temperatures as low as -4°F for one of those 12 hours.
- If the vaccine will be stored in refrigerators after transport, be sure those refrigerators have maintained temperatures between 35°F and 46°F for at least 3 to 5 days.

Assemble packing supplies

1. **Cooler.** Use hard plastic Igloo-type coolers. Attach a “Vaccines: Do Not Freeze” label to the cooler.
2. **“Conditioned” cold packs.** Condition frozen gel packs by leaving them at room temperature for 1 to 2 hours until the edges have defrosted and packs look like they’ve been “sweating.” Cold packs that are not conditioned can freeze vaccine. **Do not use dry ice.**
3. **Thermometer.** Prepare the thermometer by placing it in the refrigerator at least 2 hours before you pack the vaccine.
4. **Packing material.** Use two 2-inch layers of bubble wrap. Not using enough bubble wrap can cause the vaccine to freeze.



Pack vaccine

1. Cold packs

Spread conditioned cold packs to cover only half of the bottom of the cooler.



2. Bubble wrap

& Thermometer

Completely cover the cold packs with a 2-inch layer of bubble wrap. Then, place the thermometer/probe on top of the bubble wrap directly above a cold pack.



3. Vaccine

Stack layers of vaccine boxes on the bubble wrap. Do not let the boxes of vaccine touch the cold packs.



4. Bubble wrap

Completely cover the vaccine with another 2-inch layer of bubble wrap.



5. Cold packs

Spread “conditioned” cold packs to cover only half of the bubble wrap. Make sure that the cold packs do not touch the boxes of vaccine.



6. Form & display

Fill the cooler to the top with bubble wrap. Place the thermometer’s digital display and the *Return or Transfer of Vaccines Report* form on top. It’s ok if temperatures go above 46°F while packing.



As soon as you reach the destination site, check the vaccine temperature. If the vaccine is:

- Between 35°F and 46°F, put it in the refrigerator.
- Below 35°F or above 46°F, contact your VFC Rep or the VFC program immediately. Then label the vaccine “Do Not Use” and put it in the refrigerator.

Transporting Frozen Vaccines

Guidelines for vaccine transport in emergency situations

- Routine transport of varicella-containing vaccines (MMRV and varicella vaccine) is not allowed. These vaccines should only be moved and transported when absolutely necessary.
- Make sure you have a vaccine emergency plan that includes the name and address of the destination site where you can take your frozen vaccine in an emergency.
- If vaccines must be transported, contact your VFC Program Representative or the VFC Program.
- Varicella-containing vaccines should preferably be transported under frozen conditions (below 5F or -15C). However, the vaccine may also be transported in refrigerated conditions (35F-46 F, 2C-8C). Do not freeze diluent for varicella-containing vaccines.
- Vaccines must be placed in a freezer maintaining temperatures below 5F (-15C) immediately upon arrival at the backup storage facility.
- A Frozen Vaccine Log must be used to document and report back to the VFC program the timeframe and temperature to which vaccines were exposed during transport.

Assemble packing supplies and documents

Most emergencies happen suddenly. Be sure you are prepared for emergency transport of frozen vaccine by always having the following supplies ready.

- 1. Cooler.** Use hard plastic Igloo-type coolers.
- 2. Frozen cold packs.** Keep enough frozen cold packs in your vaccine freezer to make two layers in the transport cooler. You will need 6-8 frozen packs per cooler. NEVER USE DRY ICE.
- 3. Thermometer.** Keep a portable MIN/MAX thermometer in your vaccine freezer even if you normally use a continuous read thermometer for monitoring vaccine freezer temperatures.
- 4. Packing materials.** Use any material like bubble wrap to place on top of the frozen cold packs to prevent contents from shifting. Make sure you DO NOT place bubble wrap between the vaccine and frozen packs.
- 5. Frozen Vaccine Transport Log.** You must document the total timeframe and temperatures vaccines were exposed to during transport to and from the back-up facility. Put a copy of the log in each cooler that might be used to transport frozen vaccine.
- 6. Transporting Frozen Vaccine job aid.** Put one copy in each cooler that might be used to transport frozen vaccine.

Pack vaccines and prepare for transport

Prepare for transport

- Verify that the destination site has enough room for your vaccine and that someone will be there when the vaccine arrives.
- Verify that you have all the packing supplies on the above list.
- Complete the Frozen Vaccine Transport Log

Pack vaccines



Spread a layer of frozen ice packs to cover the bottom of the cooler. Do not use dry ice.

1



Spread another layer of frozen ice packs to cover the vaccine.

4



Stack layers of vaccine boxes directly on top of the frozen ice packs.

2



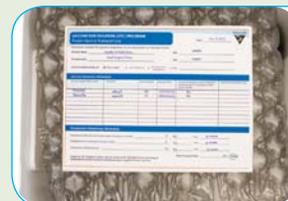
Fill the cooler to the top with insulation material (bubble wrap).

5



Place the thermometer probe with the top layer of vaccine.

3



Place the thermometer's display on top of the insulation/packing material. Place the Frozen Vaccine Transport Log on top. Then close the cooler and transport the vaccine.

6

Unpack the vaccine

When you arrive at the destination site, record the temperature of the vaccine in the cooler on the Transport Log before removing it from the cooler.