

STEP 3:

Vaccine Storage and Handling

THIS CHAPTER WILL HELP YOU prepare for your first vaccine shipment. Vaccines only work when they are viable, that is, when they are intact – undamaged and uncontaminated. To ensure vaccines are viable or potent or “good,” you must maintain them between the manufacturer-recommended temperature ranges that are not too cold or too warm. This information is available in the package insert. Although most vaccines should not be frozen, certain vaccines containing varicella vaccine virus (VAR, MMRV, and *Zostavax*) require frozen storage. In addition, several vaccines including MMR, MMRV, VAR, *Zostavax*, IPV, HPV (*Gardasil 9*), meningo-



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STEP-BY-STEP: VACCINE STORAGE AND HANDLING TASKS

- Receive vaccine shipments
 - Open package immediately
 - Assess for proper storage conditions of the vaccine shipment upon arrival
 - Store vaccines immediately at the recommended storage temperature
 - Know where to place vaccines within the refrigerator or freezer
- Monitor and record temperatures at least twice each day
 - Choosing thermometers
- If there’s a problem, take appropriate action right away; report power failures or other storage issues immediately!
- Transport vaccines properly (and only when absolutely necessary)
 - Transporting frozen varicella-containing vaccines to an offsite clinic location

coccal ACWY (*Menveo*), meningococcal B (*Bexsero*), and certain formulations of influenza vaccine (*Afluria*, *Fluad*, *Fluarix*, *Flublok*, *FluLaval*, *FluMist*, *Fluvirin*, and *Flucelvax*) should be protected from light.

Before we get started on this important topic, be sure to review the three resources shown below. The first two provide some basic information to help as you are setting up your vaccine operations, while the third is a guide that offers a wealth of information to help with almost any vaccine storage and handling issue you are likely to encounter.

- *Checklist for Safe Vaccine Storage and Handling*
www.immunize.org/catg.d/p3035.pdf
- *Don't Be Guilty of These Preventable Errors in Vaccine Storage and Handling!*
www.immunize.org/catg.d/p3036.pdf
- *Vaccine Storage and Handling Toolkit*
www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

A Little Background: Types of Vaccines and Diluents

INACTIVATED VACCINES can be composed of either killed whole viruses, or fractions of either viruses or bacteria. Inactivated vaccines are damaged by freezing. The inactivated vaccines needed by many adults include:

- tetanus, diphtheria, and pertussis (Tdap/Td);
- injectable influenza;
- pneumococcal polysaccharide and conjugate;
- human papillomavirus;
- hepatitis A and B;
- meningococcal ACWY and B vaccines; and
- zoster (shingles; *Shingrix*).

LIVE ATTENUATED VACCINES consist of a weakened form of the live virus. They are easily damaged or destroyed by heat and light. This makes it even more important that they be stored and handled with extreme care. Live attenuated vaccines available for many adults include:

- measles, mumps and rubella (MMR);
- varicella (chickenpox);
- zoster (shingles; *Zostavax*); and
- nasal spray influenza vaccine (when recommended).

DILUENTS are liquids used with some vaccines. Most vaccines are provided as a liquid that is already packaged in a syringe, or in a vial, ready to be drawn into a syringe and injected. However, some vaccines are provided as a lyophilized (freeze-dried) powder. A separate liquid (the diluent) is provided for lyophilized vaccines. The diluent must be added to the lyophilized powder before injection, a process called “reconstitution.” A lyophilized vaccine must only be reconstituted with the specific diluent provided for that vaccine; diluents are not interchangeable. Most vaccine diluents may be stored either in the refrigerator or maintained at room temperature. Check the package insert to determine appropriate storage guidance for the specific diluent you are using. Summary information may be found in the Immunization Action Coalition’s (IAC) *Vaccines with Diluents: How to Use Them*, available at www.immunize.org/catg.d/p3040.pdf.

Receive vaccine shipments

Open package immediately

Vaccine deliveries should be made only when your vaccine coordinator or backup person is present. But it is important for everyone in your clinic – especially your front desk staff or any individuals who receive deliveries – to know how important it is to store these *fragile* vaccines promptly when they arrive. Don’t let a vaccine package sit at the front desk or outside your front or back door!

It is important for *everyone* in your clinic... to know how important it is to store these *fragile* vaccines promptly when they arrive.

Assess for proper storage conditions of the vaccine shipment upon arrival

Packages should be opened and inspected immediately for any damage and to determine if the packages seem too warm or too cold to the touch. Examine temperature indicators if they are included in the box. Check the vaccine quantities, lot numbers, and expiration dates against the packing slip. If there are discrepancies, contact the source of the shipment (e.g., manufacturer, distributor, state health department) immediately.

When your shipments arrive, check to see that the ***inactivated vaccines are cold but not frozen***, and that the ***varicella and Zostavax vaccines are frozen***. MMR vaccine may be refrigerated or frozen. Nasal spray influenza vaccine is refrigerated. If a temperature indicator (often, this is a temperature-sensitive strip that changes colors) is included in the shipment, check it to see if appropriate temperatures have been maintained. Not all shipments will contain a temperature indicator. That’s acceptable if the shipments have been packed according to certain FDA-approved packing standards. But make

If the product seems to have been exposed to too-high or too-low (i.e., frozen) temperatures or something seems amiss, put the vaccine in a specially marked, segregated area or tray in the refrigerator or freezer.

sure the container included appropriate insulation and gel packs or ice packs and that any ice packs have not completely thawed. If the product seems to have been exposed to too-high or too-low (i.e., frozen) temperatures or something seems amiss, put the vaccine in a specially marked, segregated area or tray in the refrigerator or freezer (whichever is indicated according to the type of vaccine delivered). Call the source of your shipment (e.g., manufacturer, distributor, state health department) for advice about what to do next.

Store vaccines immediately at the recommended storage temperature

Most vaccines (all inactivated vaccines and live nasal spray influenza vaccine) must be stored between 2° to 8°C (36° to 46°F), which is the recommended refrigerator temperature. Live varicella (chickenpox) and *Zostavax* (shingles) vaccines must be stored frozen between -50° to -15°C (-58° to +5°F). These vaccines may be temporarily stored in a refrigerator (between 2° to 8°C [36° to 46°F]) for up to 72 hours before use, if they have not been reconstituted and will be used within that time period.

If they are not used within 72 hours, they must be discarded. Once these vaccines have been stored in the refrigerator, they must not be refrozen; once they have been reconstituted, you have only 30 minutes in which to administer these sensitive vaccines before they lose potency and cannot be used. Bottom line – don't remove these vaccines from the freezer or reconstitute them until you have your

It is critical to keep each vaccine at its proper storage temperature.

patient sitting in front of you! (More information on this subject is located in *Step 5: Administering Vaccines.*)

The live MMR vaccine can be stored in *either* the freezer or the refrigerator. However, once the vaccine has been drawn into the syringe, it must be used within 8 hours or discarded.



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It is critical to keep each vaccine at its proper storage temperature. A simple sign on the refrigerator and freezer can remind you where each vaccine goes. For example, the Immunization Action Coalition's (IAC) handy *Vaccine Handling Tips*, available at

www.immunize.org/catg.d/p3048.pdf, can be posted on your refrigerator and freezer doors to remind staff of the appropriate storage temperatures and other basics of good vaccine management.

Remember, when vaccines get too warm or too cold, you can't tell by looking or feeling if they have been damaged. That's why it's so critical to monitor and record the temperatures inside your refrigerator and freezer at least twice each day to make sure they are within the proper range. If the temperature goes out of range, you must take immediate steps to respond to the situation. IAC's *Vaccine Storage Troubleshooting Record*, available at www.immunize.org/catg.d/p3041.pdf, offers guidance to help you determine what should be done in this situation.

Know where to place vaccines within the refrigerator or freezer

Vaccines should always be stored in the middle of the refrigerator or freezer – never in the doors.

Vaccine should always be stored in the middle of the refrigerator or freezer – never in the doors.

Why? Because items stored in the door are frequently exposed to warm temperatures when the unit is opened. CDC's “best storage practice” is to place the vaccines in the center refrigerator space, contained in the original packaging, inside design-

ated storage trays positioned 2 to 3 inches from refrigerator walls. Also, be sure to keep older vaccines toward the front of the shelf. When new product arrives, “rotate your stock” by placing the newer vaccines behind the older ones. This will help ensure that vaccines with the earliest (soonest) expiration dates are used first. CDC has developed informative labels you can print and use to help organize vaccine placement in your refrigerator or freezer. These labels are found at www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf.

Checking Expiration Dates

Be aware that if the expiration date on the vial consists of just a month and a year (e.g., “12/18”), the vaccine may be used until the last day of December 2018. In this case, the expiration month includes the whole month. If a full date is included (e.g., 9/15/18), then the vaccine should not be used after the printed date. The Centers for Disease Control and Prevention's (CDC) *Vaccine Storage and Handling Toolkit*, available at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf, provides additional information about reading vaccine labels and determining expiration dates. Never use a vaccine that has been contaminated or has expired! If an expired vaccine – even 1 day expired – is administered to a patient, the dose must be repeated.



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Monitor and record temperatures at least twice each day

As you set up your refrigerator and freezer, you should take steps to help stabilize and maintain the proper temperatures in both units. You should place at least two or three containers (for example, plastic liter or gallon bottles) of water in areas of the refrigerator where vaccine cannot be stored, such as in the doors. Similarly, you should keep several frozen water bottles in the freezer to help maintain the cold temperature in the event of a power outage. Get in the habit of periodically checking the gasket seals of your refrigerator and freezer units. These seals must be intact to ensure that the door always closes completely.

You also should post the appropriate temperature log sheets (both Celsius and Fahrenheit versions are available through the links shown below) on your refrigerator and freezer.

C Celsius

REFRIGERATOR

www.immunize.org/catg.d/p3037C.pdf

FREEZER

www.immunize.org/catg.d/p3038C.pdf

F Fahrenheit

REFRIGERATOR

www.immunize.org/catg.d/p3037F.pdf

FREEZER

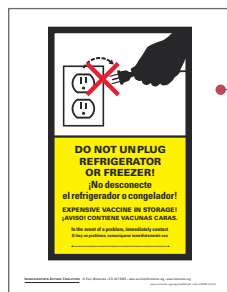
www.immunize.org/catg.d/p3038F.pdf

Use the appropriate logs to document your twice-each-day checks (first thing in the morning and late afternoon before closing) of the temperatures in your vaccine storage units. And remember to pay attention to the temperatures you're recording on these logs. It's easy to get in the habit of writing without noticing, even when the temperature you have

Remember to pay attention to the temperatures you're recording on these logs.

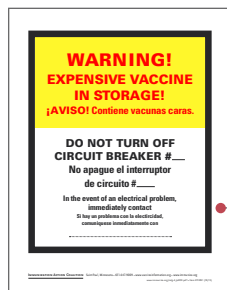
just written down is out of range and requires action. If you note an out-of-range temperature, consult the *Vaccine Storage Troubleshooting Record* at www.immunize.org/catg.d/p3041.pdf for guidance on appropriate actions to take.

Loss of power to a refrigerator or freezer can happen in a number of ways. The one that is easiest to avoid is loss of power at the plug. For example, maintenance workers or others might pull the plug from the socket to free it for a “temporary” use, such as using electrical equipment to clean the floors. Make sure this doesn't happen in your facility! One of the simplest ways to prevent this problem is to apply a bright and easily understood “Do Not Unplug” sign (www.immunize.org/catg.d/p2090.pdf) right above the electrical outlet.



www.immunize.org/catg.d/p2090.pdf

It also helps to put a “Do Not Turn Off Circuit Breaker” sign (www.immunize.org/catg.d/p2091.pdf) by the breaker box so that someone doesn't inadvertently cut off the power supply to the vaccine storage units.



www.immunize.org/catg.d/p2091.pdf

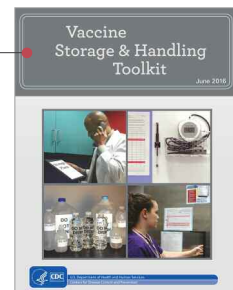
Choosing thermometers

Thermometers are a critical part of good storage and handling practice. A storage unit is only as effective as the temperature monitoring system inside. An accurate temperature history that reflects the actual vaccine temperatures is imperative to effective vaccine management.

Every freezer and refrigerator unit used to store vaccine should have a calibrated thermometer. CDC recommends using only calibrated thermometers with a Certificate of Traceability and Calibration Testing (“Report of Calibration”). This certificate informs the user about a thermometer's level of accuracy compared to a recognized standard.

Before purchasing thermometers for your refrigerator and freezer units, you should review the extensive information about thermometers found in CDC's *Vaccine Storage and Handling Toolkit* (*Toolkit*), available at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf



In general, CDC recommends thermometers that measure temperatures constantly (e.g., a continuous monitoring and recording digital data logger or “DDL”) and use a probe inserted into a glycol-filled bottle. This arrangement more closely approximates the vaccine vial temperature than measuring the more variable temperature of the air in the storage unit. CDC also recommends the thermometer have an alarm for out-of-range temperature and be capable of showing the current temperature as well as the minimum and maximum temperatures reached during a designated period of time. CDC

Be sure to check the CDC *Toolkit* for answers to your questions about choosing thermometers. State and local health department immunization programs also are excellent resources for information about thermometers.

does not recommend using: fluid-filled biosafe liquid thermometers, bi-metal stem thermometers, food thermometers, household thermometers, chart recorders, infrared thermometers, or thermometers that are not calibrated.

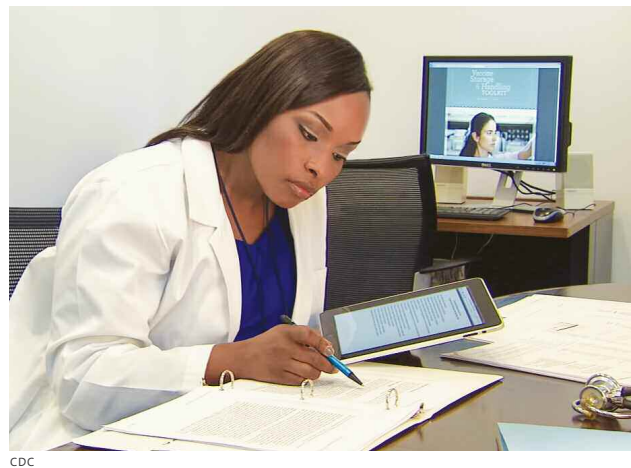
Be sure to check the CDC *Toolkit* for answers to your questions about choosing thermometers. State and local health department immunization programs also are excellent resources for information about thermometers. Providers who receive Vaccines for Children (VFC) vaccines or other vaccines purchased with public funds should consult their immunization program regarding thermometer recommendations and requirements.

If there's a problem, take appropriate action right away; report power failures or other storage issues immediately!

Power failures happen. It's crucial that your clinic fosters a culture of openness about reporting interruptions in the power supply or other vaccine mishaps. First, it's a matter of ethics. You don't want to administer vaccine of questionable viability to anyone. And you certainly don't want to be placed in the position of having to recall patients and re-administer vaccines. Finally, if problems are reported promptly, actions may be taken and you may be able to salvage the affected vaccines.

If you suspect that vaccines have been exposed to out-of-range temperatures or have been left out of the refrigerator or freezer, mark those vaccine vials with "Do Not Use" and transfer them to a functioning refrigerator or freezer at the proper storage

temperature as soon as possible, while you are determining if the vaccine is still viable. If the problem is a faulty refrigerator or freezer, immediately record the temperature inside the affected unit to help determine the timeframe of the exposure. This is when using the recommended type of thermometer really pays off! If you have been using a continuously recording thermometer, you can review information from the thermometer to determine when the temperature problem began. A thermometer that records minimum and maximum



CDC

temperatures will indicate the lowest and highest temperatures recorded since you last reset it. This information can be invaluable in helping determine if the vaccine may still be viable. If the vaccines were inadvertently left out at room temperature or were left in some other improper storage condition (e.g., temperatures that are too warm or too cold), record the length of time that may have elapsed. Be sure to immediately notify the clinic supervisor and vaccine coordinator about what has happened. Then your vaccine coordinator will contact your state or local health department and / or the manufacturer to discuss the situation and determine an appropriate course of action.



CDC

Be sure to check out IAC's *Vaccine Storage Troubleshooting Record* at www.immunize.org/catg.d/p3041.pdf and *Emergency Response Worksheet* at www.immunize.org/catg.d/p3051.pdf for quick guidance on what to do when you discover vaccine storage outside the recommended temperature range.

www.immunize.org/catg.d/p3051.pdf

If you are told that the vaccines should not be used, use a permanent black marker to write “nonviable” on the glass or label and remove them from the refrigerator or freezer so that they aren’t administered by mistake. Ask your state health department or manufacturer(s) how you should dispose of the nonviable vaccine.

 The image shows a form titled "Emergency Response Worksheet". It contains several sections: "What is the type of event (leak or other event) that results in vaccine storage outside of the recommended temperature range?", "Vaccine Storage in Refrigerator", and "Vaccine Stored in Freezer". Each section has a table with columns for "Vaccine", "Quantity", "Lot", "Expiration Date", "Storage Temperature", and "Action". There are also sections for "Vaccine Storage Temperature" and "Vaccine Storage Location".

Transport vaccines properly (and only when absolutely necessary)

Vaccine manufacturers generally do not recommend or provide guidance for transport of vaccines. But during an emergency, or if you host an offsite vaccination clinic, you may need to transport vaccines from one place to another. It is critical that you maintain and monitor the vaccine cold chain during these activities. (See special information for frozen varicella-containing vaccines in the next paragraph.)

You will need at least one insulated container (see *Step 2: Setting Up for Vaccination Services*) with a thermometer to place near the vaccine. Think of this container as your clinic’s vaccine storage area in miniature: you’ll need to monitor it with a temperature log as well, just like you do when in the office. CDC’s *Vaccine Storage and Handling Toolkit*, available at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf, devotes several pages to the topic of transporting vaccines.

Neither CDC nor the vaccine manufacturer recommends transporting frozen varicella-containing vaccines.

Transporting frozen varicella-containing vaccines to an offsite clinic location

Neither CDC nor the vaccine manufacturer recommends transporting frozen varicella-containing vaccines. But if these vaccines must be moved (for example, during an emergency), they should be transported in a portable freezer unit that maintains the temperature range of -50° to -15°C (-58° to $+5^{\circ}\text{F}$). Portable freezer units may be available for rent in some locations. But if frozen varicella-containing vaccines must be transported and a portable freezer unit is not available, do NOT use dry ice, as this actually could allow the vaccines to become too cold. This in turn could affect the vial seal and possibly allow outside air to enter the vial. If frozen varicella-containing vaccines are transported at refrigerated temperatures (2° to 8°C [36° to 46°F]), they must be discarded if they have not been used within 72 hours.

This chapter has covered the basic steps involved in vaccine storage and handling for adult vaccines. Be sure you print up the forms, establish policies, and select someone in your office to be in charge of vaccines. Now, let’s vaccinate!

STEP 3: VACCINE STORAGE AND HANDLING

Materials and Resources for You to Use

► TOOLS FOR PROVIDERS

Checklist for Safe Vaccine Storage and Handling (IAC) – www.immunize.org/catg.d/p3035.pdf

Do Not Turn Off Circuit Breaker – sign (IAC)
www.immunize.org/catg.d/p2091.pdf

Do Not Unplug – sign (IAC)
www.immunize.org/catg.d/p2090.pdf

Don't Be Guilty of These *Preventable* Errors in Vaccine Storage and Handling! (IAC)
www.immunize.org/catg.d/p3036.pdf

Emergency Response Worksheet (IAC)
www.immunize.org/catg.d/p3051.pdf

Temperature Log for Freezer – Celsius (IAC)
www.immunize.org/catg.d/p3038C.pdf

Temperature Log for Freezer – Fahrenheit (IAC)
www.immunize.org/catg.d/p3038F.pdf

Temperature Log for Refrigerator – Celsius (IAC)
www.immunize.org/catg.d/p3037C.pdf

Temperature Log for Refrigerator – Fahrenheit (IAC)
www.immunize.org/catg.d/p3037F.pdf

NOTE: The publisher of each resource is shown as an acronym in the parentheses following the title. A key to these acronyms is included in *Appendix A: Acronyms and Abbreviations*.

Vaccine Handling Tips (IAC)
www.immunize.org/catg.d/p3048.pdf

Vaccine Storage Troubleshooting Record (IAC)
www.immunize.org/catg.d/p3041.pdf

Vaccines with Diluents: How to Use Them (IAC)
www.immunize.org/catg.d/p3040.pdf

► ADDITIONAL PROVIDER RESOURCES

Vaccine Storage and Handling Toolkit (CDC)
www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

Vaccine Storage and Handling Web Section (CDC)
www.cdc.gov/vaccines/recs/storage/default.htm

Vaccine Storage and Handling Web Section (IAC)
www.immunize.org/handouts/vaccine-storage-handling.asp

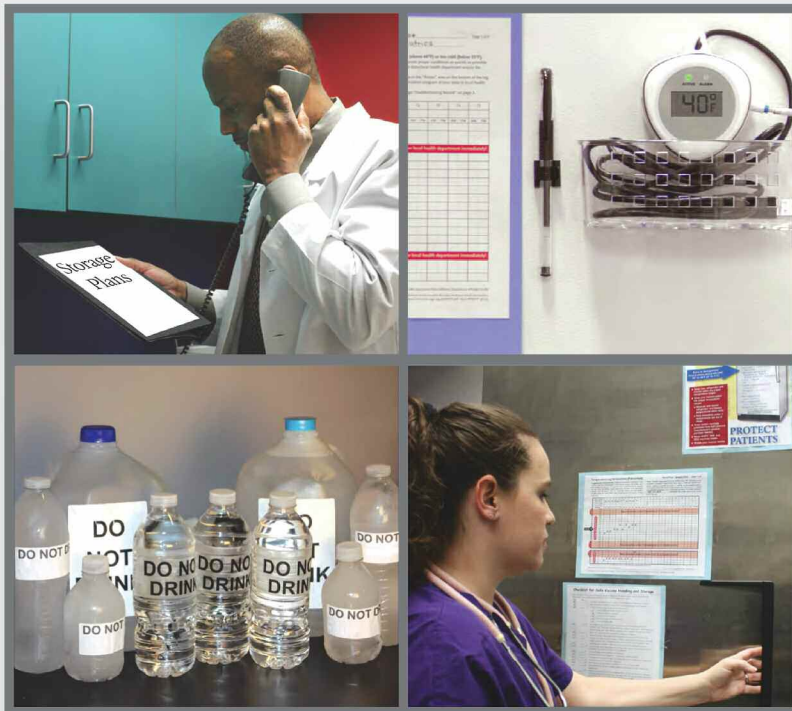
► GENERAL INFORMATION

Immunization Action Coalition (IAC)
www.immunize.org

To access the current, ready-to-copy version of this toolkit, visit
[www.cdc.gov/vaccines/hcp/admin/storage/toolkit/
storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)

Vaccine Storage & Handling Toolkit

June 2016



The
CDC Toolkit
is 82 pages in
length.



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

To access the current, ready-to-copy versions of these temperature logs, visit www.immunize.org/handouts/temperature-logs.asp

Celsius

C Temperature Log for Refrigerator – Celsius
DAYS 1-15

Month/Year _____ VFC PIN or other ID # _____ Page 1 of 1
Facility Name _____

Monitor temperatures closely!

- Write your initials below in "Staff Initials," and note the time in "Exact Time."
- Record temps twice each workday.
- Record the min/max temps once each workday – preferably in the morning.
- Put an "X" in the row that corresponds to the refrigerator's temperature.
- If any out-of-range temps, see instructions to the right.
- After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range – too warm (above 8°C) or too cold (below 2°C).

- Label exposed vaccines "do not use," and store in under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
- Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
- Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
- Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
TEMPERATURES	8°C														
	7°C														
	6°C														
	Aim for 5°C														
	4°C														
	3°C														
2°C															
ACTION	Write any out-of-range temps (above 8°C or below 2°C) in below 30" box.														
	Room Temperature														

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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Fahrenheit

F Temperature Log for Refrigerator – Fahrenheit
DAYS 1-15

Month/Year _____ VFC PIN or other ID # _____ Page 1 of 1
Facility Name _____

Monitor temperatures closely!

- Write your initials below in "Staff Initials," and note the time in "Exact Time."
- Record temps twice each workday.
- Record the min/max temps once each workday – preferably in the morning.
- Put an "X" in the row that corresponds to the refrigerator's temperature.
- If any out-of-range temps, see instructions to the right.
- After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range – too warm (above 48°F) or too cold (below 36°F).

- Label exposed vaccines "do not use," and store under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
- Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
- Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
- Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
TEMPERATURES	48°F														
	45°F														
	44°F														
	43°F														
	42°F														
	41°F														
Aim for 40°F															
39°F															
38°F															
37°F															
36°F															
ACTION	Write any out-of-range temps (above 48°F or below 36°F) in below 30" box.														
	Room Temperature														

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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Refrigerator www.immunize.org/catg.d/p3037C.pdf

Refrigerator www.immunize.org/catg.d/p3037F.pdf

C Temperature Log for Freezer – Celsius
DAYS 1-15

Month/Year _____ VFC PIN or other ID # _____ Page 1 of 1
Facility Name _____

Monitor temperatures closely!

- Write your initials below in "Staff Initials," and note the time in "Exact Time."
- Record temps twice each workday.
- Record the min/max temps once each workday – preferably in the morning.
- Put an "X" in the row that corresponds to the freezer's temperature.
- If any out-of-range temps, see instructions to the right.
- After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

- Label exposed vaccines "do not use," and store in under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
- Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
- Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
- Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
TEMPERATURES	-15°C														
	-16°C														
	-17°C														
	-18°C														
	-19°C														
	-20°C														
-21°C															
-22°C															
-50°C to -53°C															
ACTION	Write any out-of-range temps (above -15°C or below -50°C) in below 30" box.														
	Room Temperature														

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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F Temperature Log for Freezer – Fahrenheit
DAYS 1-15

Month/Year _____ VFC PIN or other ID # _____ Page 1 of 1
Facility Name _____

Monitor temperatures closely!

- Write your initials below in "Staff Initials," and note the time in "Exact Time."
- Record temps twice each workday.
- Record the min/max temps once each workday – preferably in the morning.
- Put an "X" in the row that corresponds to the freezer's temperature.
- If any out-of-range temps, see instructions to the right.
- After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).

- Label exposed vaccines "do not use," and store in under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
- Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
- Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
- Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
TEMPERATURES	5°F														
	4°F														
	3°F														
	2°F														
	1°F														
	0°F														
-1°F															
-2°F															
-3°F															
-4°F															
-58°F to -5°F															
ACTION	Write any out-of-range temps (above 5°F or below -58°F) in below 30" box.														
	Room Temperature														

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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Freezer www.immunize.org/catg.d/p3038C.pdf

Freezer www.immunize.org/catg.d/p3038F.pdf

To access the current, ready-to-copy version of this piece, visit

www.immunize.org/catg.d/p3035.pdf

Checklist for Safe Vaccine Storage and Handling

Are you doing everything you should to safeguard your vaccine supply? Review this list to see where you might make improvements in your vaccine management practices. Check each listed item with either **YES** or **NO**.

Establish Storage and Handling Policies

- YES NO 1. We have designated a primary vaccine coordinator and at least one alternate coordinator to be in charge of vaccine storage and handling at our facility.
- YES NO 2. Both the primary and alternate vaccine coordinator(s) have completely reviewed either CDC's Vaccine Storage & Handling Toolkit (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf) or equivalent training materials offered by our state or local health department's immunization program.
- YES NO 3. We have detailed, up-to-date, written standard operating procedures for general vaccine management, including procedures for routine activities and an emergency vaccine retrieval and storage plan for power outages and other problems. Our procedures are based on CDC's Vaccine Storage & Handling Toolkit and/or on instruction from our state or local health department's immunization program.
- YES NO 4. We review these policies with all staff annually and with new staff, including temporary staff, when they are hired.

Log In New Vaccine Shipments

- YES NO 5. We maintain a vaccine inventory log that we use to document the following:
 - YES NO a. Vaccine name and number of doses received
 - YES NO b. Date we received the vaccine
 - YES NO c. Condition of vaccine when we received it
 - YES NO d. Vaccine manufacturer and lot number
 - YES NO e. Vaccine expiration date

Use Proper Storage Equipment

- YES NO 6. We store vaccines in separate, self-contained units that refrigerate or freeze only. If we must use a house-hold-style combination unit, we use it only for storage of our refrigerated vaccines, maintaining frozen vaccines in a separate stand-alone freezer.
- YES NO 7. We store vaccines in units with enough room to maintain the year's largest inventory without crowding.
- YES NO 8. We never store any vaccines in a dormitory-style unit (a small combination freezer-refrigerator unit with the freezer compartment inside the refrigerator).
- YES NO 9. We use only calibrated thermometers that have a Certificate of Calibration Testing* ("Report of Calibration") and are calibrated every 1 to 2 years from the last calibration testing date or according to the manufacturer's suggested timeline.
- YES NO 10. We have planned back-up storage unit(s) in the event of a power failure or other unforeseen event.

*Certificate of Calibration Testing ("Report of Calibration") with calibration measurements traceable to a laboratory with accreditation from the International Laboratory Accreditation Cooperations (ILAC) Mutual Recognition Arrangement (MRA) signatory body.



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CONTINUED ON THE NEXT PAGE ►

Vaccine Storage and Handling (continued)

page 2 of 3

Ensure Optimal Operation of Storage Units

have a "Do Not Unplug" sign (e.g., www.immunize.org/catg.d/p2090.pdf) next to the electrical outlets the refrigerator and freezer and a "Do Not Stop Power" warning label (e.g., www.immunize.org/catg.d/p91.pdf) by the circuit breaker for the electrical outlets. Both signs include emergency contact information. perform regular maintenance on our vaccine storage units to assure optimal functioning. For example, we p the units clean, dusting the coils and cleaning beneath the units as recommended by the manufacturer.

Maintain Correct Temperatures

always keep at least one accurate calibrated thermometer (+/-0.5°C [+/-1°F]) with the vaccines in the refrigerator and a separate calibrated thermometer with the vaccines in the freezer.
 use a thermometer that
 uses an active display to provide continuous monitoring information.
 is digital and has a detachable probe that has been buffered against sudden temperature changes by being immersed in a vial filled with liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads), or a solid block of material (e.g., aluminum, Teflon®).
 includes an alarm for out-of-range temperatures.
 has a digital data logger that indicates current, minimum, and maximum temperatures.
 can measure temperatures within +/-0.5°C (+/-1°F).
 has a low-battery indicator.
 maintain the refrigerator temperature at 2–8°C (36–46°F), and we aim for 5°C (40°F).
 maintain the freezer temperature between -50°C and -15°C (-58°F and +5°F).
 set the thermostat for the refrigerator and the freezer at the factory-set or midpoint temperatures.

check the door and/or on the floor of the unit temperatures. We keep ice packs, ice-filled containers, and have frozen emergency.

page 3 of 3

temperatures) review the temperature logs weekly.

on the doors of the refrigerator and freezer refrigerator and which in the freezer.

it.
 r (away from walls and vents), leaving room temperature in the doors.

ge unit, and we do not store vaccines in these

ore vaccines only in the refrigerator section outlet that leads from the freezer to the

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refrigerator (often near the top shelf). In general, we try to avoid storing vaccines on the top shelf, and we place water bottles in this location.

- YES NO 32. We check vaccine expiration dates and rotate our supply of each type of vaccine so that vaccines with the earliest expiration dates are located close to the front of the storage unit, facilitating easy access.
- YES NO 33. We store vaccines in their original packaging in clearly labeled uncovered containers.

Take Emergency Action As Needed

- YES NO 34. In the event that vaccines are exposed to improper storage conditions, we take the following steps:
 - YES NO a. We restore proper storage conditions as quickly as possible. If necessary, we label the vaccine "Do Not Use" and move it to a unit where it can be stored under proper conditions. We do not discard the vaccine before discussing the circumstances with our state/local health department and/or the appropriate vaccine manufacturers.
 - YES NO b. We follow the Vaccine Storage Troubleshooting Record's (www.immunize.org/catg.d/p3041.pdf) instructions for taking appropriate action and documenting the event. This includes recording details such as the length of time the vaccine was out of appropriate storage temperatures and the current room temperature, as well as taking an inventory of affected vaccines.
 - YES NO c. We contact our clinic supervisor or other appropriate clinic staff to report the incident. We contact our state/local health department and/or the appropriate vaccine manufacturers for consultation about whether the exposed vaccine can still be used.
 - YES NO d. We address the storage unit's mechanical or electrical problems according to guidance from the unit's manufacturer or a qualified repair service.
 - YES NO e. In responding to improper storage conditions, we do not make frequent or large changes in thermostat settings. After changing the setting, we give the unit at least a day to stabilize its temperature.
 - YES NO f. We do not use exposed vaccines until our state/local health department's immunization program or the vaccine manufacturer has confirmed that the vaccine is acceptable for use. We review this information with our clinic medical director before returning the vaccine to our supply. If the vaccine is not acceptable for use, we follow our state/local health department instructions for vaccine disposition.

If we answer **YES** to all of the above, we give ourselves a pat on the back! If not, we assign someone to implement needed changes!

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Don't Be Guilty of These Preventable Errors in Vaccine Storage and Handling (continued)

page 2 of 2

ERROR: Inadvertently cutting the power supply to the storage units

- Be sure everyone in your office, including the janitorial staff, understands that very expensive and fragile vaccines are being stored in the refrigerator and freezer.
- Post a *Do Not Unplug* sign (www.immunize.org/catg.d/p3036.pdf)

ERROR: Discarding temperature logs too soon

- Keep your temperature logs for at least 3 years. Why?
- You can track recurring problems as the storage unit ages.
 - If out-of-range temperatures have been documented, you can determine how long and how often this has been occurring.

Don't Be Guilty of These Preventable Errors in Vaccine Storage and Handling!

Do you see your clinic or practice making any of these frequently reported errors in vaccine storage and handling? Although some of these errors are much more serious than others, none of them should occur. Be sure your healthcare setting is not making any of these preventable errors.

ERROR: Designating only one person, rather than at least two, to be responsible for storage and handling of vaccines

- Everyone in the office should know the basics of vaccine handling, including what to do when a shipment arrives and what to do in the event of an equipment failure or power outage.
- Train at least one back-up person. The back-up and primary persons should be equally familiar with all aspects of vaccine storage and handling, including knowing how to handle vaccines when they arrive, properly record refrigerator and freezer temperatures, what to do when an out-of-range temperature occurs, and how to appropriately respond to an equipment problem or power outage.

ERROR: Storing vaccine inappropriately

- Be sure all office staff (especially persons involved in receiving vaccine shipments) understand the importance of properly storing vaccines immediately after they arrive.
- Know which vaccines should be refrigerated and which should be frozen. Storage information is found in the package insert. For quick reference, post IAC's *Vaccine Handling Tips* (www.immunize.org/catg.d/p3048.pdf) on the refrigerator and freezer.
- Always store vaccines (and thermometers) in the body of the refrigerator – not in the vegetable bins, on the floor, next to the walls, in the door, or near the cold air outlet from the freezer. The temperature in these areas may differ significantly from the temperature in the body of the unit.
- Don't over-pack the unit. Place the vaccine packages in such a way that air can circulate around the compartment.
- Always store vaccines in their original packaging.

ERROR: Using the wrong type of equipment

STORAGE UNITS

- CDC recommends storing vaccines in separate, self-contained units that only refrigerate or only freeze. If a combination refrigerator/freezer must be used, only refrigerated vaccines should be stored in the unit, and a separate stand-alone freezer should be used for frozen vaccines.
- Never store vaccines in a "dormitory-style" unit (i.e., a small refrigerator-freezer unit with one exterior door and a freezer compartment inside the refrigerator). These units cannot maintain stable temperatures.

THERMOMETERS

- Use only calibrated thermometers that have a Certificate of Traceability and Calibration Testing. Ideally, you should use a "continuous read" thermometer that records temperatures all day and all night.
- Place the thermometer's temperature probe in glycol so that you are not just measuring air temperature, which is subject to fluctuation when you open the door.

For more detailed information, see the *Vaccine Storage Equipment* section of CDC's *Vaccine Storage and Handling Toolkit* (www.cdc.gov/vaccines/recs/storage/toolkit).

ERROR: Inadvertently leaving the refrigerator or freezer door open or having inadequate seals

- Unfortunately, too much vaccine is lost every year because storage unit doors were left open. Remind staff to *completely* close the door every time they open the refrigerator or freezer.
- Check the seals on the doors on a regular schedule, such as when you're taking inventory. If there is any indication the door seal may be cracked or not sealing properly, have it replaced. (This is much less costly than replacing a box of pneumococcal conjugate or varicella vaccine!)

ERROR: Storing food and drinks in the vaccine refrigerator

- Frequent opening of the refrigerator door to retrieve food items can adversely affect the internal temperature of the unit and damage vaccines. Store only vaccines in the designated units.

CONTINUED ON THE NEXT PAGE ►



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Using vaccine with the soonest expiration

When you receive a new shipment of vaccine:

- Sort the vaccines with the shortest expiration date to the front of the unit so it is easier for staff to access this vaccine first.
- Use the "first" vaccine to be used first.

Storing vaccine inappropriately with expired vaccines

When you receive a new shipment of vaccine:

- Sort the vaccines with the shortest expiration date to the front of the unit.

When you receive a new shipment of vaccine:

- Immediately remove them from the unit so that they are not inadvertently administered.

Using multidose vials prematurely

Multidose vials of vaccines contain a preservative to prevent contamination until the expiration date on the vial, unless the vial is contaminated or the vials are not stored under appropriate conditions. However, multidose vials of certain vaccines (e.g., meningococcal polysaccharide vaccine) must be used within a defined period after opening. Refer to the package inserts for information.

The FDA has clarified that vaccines are an exception to the usual "28-day rule" for use of medications. Providers are directed to follow guidance from vaccine manufacturers.

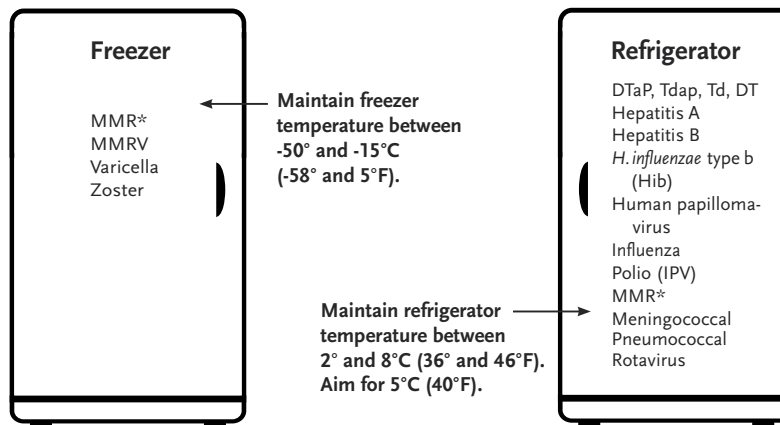
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To access the current, ready-to-copy version of this piece, visit

www.immunize.org/catg.d/p3048.pdf

Vaccine Handling Tips

REMEMBER: Improperly stored or outdated vaccines won't protect your patients!



Manage vaccine inventories.

Inventory your vaccine supplies at least monthly and before placing an order. Expired vaccine must never be used and it becomes “cash in the trash!”

Always use the vaccine with the soonest expiration date first.

Move vaccine with the soonest expiration date to the front of the storage unit and mark it to be used first. These actions help ensure it will be picked up first by someone selecting vaccine from the unit.

Store vaccine appropriately.[†]

Place vaccines in refrigerator or freezer immediately upon receiving shipment. Keep vaccine vials in their original packaging. Place vaccine in clearly labeled wire baskets or other open containers with a 2–3" separation between baskets and 4" from wall of unit. Separate or clearly mark vaccines to distinguish those that were supplied from your state's Vaccines for Children program (or other state-funded source) from those that were privately purchased. Do not store vaccines in the door or on the floor of the unit.

Stabilize temperatures.

Store ice packs in the freezer and large jugs of water in the refrigerator along with the vaccines. This will help maintain a stable, cold temperature in case of a power failure or if the refrigerator or freezer doors are opened frequently or are accidentally left open. Because frequent opening of either the refrigerator or freezer door can lead to temperature variations that could affect vaccine efficacy, you should not store food or beverages in the refrigerator or freezer.

Safeguard the electrical supply to the refrigerator.

Make sure the refrigerator and freezer are plugged into outlets in a protected area where they cannot be disconnected accidentally. Label the refrigerator, freezer, electrical outlets, fuses, and circuit breakers on the power circuit with information that clearly identifies the perishable nature of vaccines and the immediate steps to be taken in case of interruption of power.[‡] If your building has auxiliary power, use the outlet supplied by that system.

*MMR may be stored in either the freezer or the refrigerator.

[†] Refer to package insert for specific instructions on the storage of each vaccine. If you have questions about the condition of the vaccine upon arrival, immediately place the vaccine in recommended storage, mark it “do not use,” and then call your state health department or the vaccine manufacturer(s) to determine whether the potency of the vaccine(s) has been affected. For other questions, call the immunization program at your state or local health department.

[‡] For easy help with labeling units and power supplies, see IAC signs “Do Not Unplug Refrigerator or Freezer” (www.immunize.org/catg.d/p2090.pdf) and “Do Not Stop Power to Circuit Breaker” (www.immunize.org/catg.d/p2091.pdf). For guidance on steps to take during a power interruption, see IAC’s “Emergency Response Worksheet” (www.immunize.org/catg.d/p3051.pdf).

To access the current, ready-to-copy version of this piece, visit

www.immunize.org/catg.d/p3041.pdf

Vaccine Storage Troubleshooting Record (check one) Refrigerator Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated or frozen vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

Date & Time of Event <small>If multiple, related events occurred, see Description of Event below.</small>	Storage Unit Temperature <small>at the time the problem was discovered</small>		Room Temperature <small>at the time the problem was discovered</small>	Person Completing Report	
	<small>When recording temperatures, indicate F (Fahrenheit) or C (Celsius).</small>				
Date:	Temp when discovered:		Temp when discovered:	Name:	
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:
Description of Event (<i>If multiple, related events occurred, list each date, time, and length of time out of storage.</i>) <ul style="list-style-type: none"> General description (i.e., what happened?) Estimated length of time between event and last documented reading of storage temperature in acceptable range (36° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer) Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record) At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? Include any other information you feel might be relevant to understanding the event. 					
Action Taken (<i>Document thoroughly. This information is critical to determining whether the vaccine might still be viable!</i>) <ul style="list-style-type: none"> When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with local health department and/or the manufacturer[s].) Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) IMPORTANT: What did you do to prevent a similar problem from occurring in the future? 					
Results <ul style="list-style-type: none"> What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.) 					

The form includes 6 filled-in example pages.

Vaccine Storage Troubleshooting Record (check one) Refrigerator Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges. A fillable troubleshooting record (i.e., editable pdf) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event <small>If multiple, related events occurred, see Description of Event below.</small>	Storage Unit Temperature <small>at the time the problem was discovered</small>		Room Temperature <small>at the time the problem was discovered</small>	Person Completing Report	
Date: (see below)	Temp when discovered: 45°F		Temp when discovered: 77°F	Name: Nancy Nurse	
Time: (see below)	Minimum temp: 38°F	Maximum temp: 53°F	Comment (optional): temp is approx.	Title: VFC Coordinator	Date: 6/24/13
Description of Event (<i>If multiple, related events occurred, list each date, time, and length of time out of storage.</i>) <ul style="list-style-type: none"> General description (i.e., what happened?) Estimated length of time between event and last documented reading of storage temperature in acceptable range (36° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer) Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record) At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? Include any other information you feel might be relevant to understanding the event. <p>At 8 am on Monday (6/24/13) morning when clinic opened, identified 4 temperature excursions over the weekend in refrigerator with readings as high as 54°, 50°, 49° & 53°F in primary vaccine storage unit #1. Recordings taken every 15 min on calibrated digital data logger overnight. Data logger probe in glycol located in middle of refrigerator with vaccines.</p> <p>Total time out of range: approximately 3 hrs — maximum temp 53°F (see attached document of continuous temp readings)</p> <p>Inventory of vaccines: see attached</p> <p>Water bottles in refrigerator door. No vaccine stored in freezer. No problems with storage unit prior to Saturday night. Thunderstorms in area over weekend may have affected power.</p>					
Action Taken (<i>Document thoroughly. This information is critical to determining whether the vaccine might still be viable!</i>) <ul style="list-style-type: none"> When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].) Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) IMPORTANT: What did you do to prevent a similar problem from occurring in the future? <p>Vaccines currently stored appropriately at 40°F. Refrigerator and vaccines labeled "Do Not Use."</p> <p>My State Immunization Program contacted at 8:30 am. Spoke with Victor Vaccine. Provided Victor with details of event and list of vaccines. Vaccine to remain quarantined until we hear back from Victor.</p> <p>Called electric company and confirmed 2 short power outages during weekend.</p> <p>Checked refrigerator seals — called refrigerator maintenance company to replace seals.</p> <p>Checked plug on unit — placed tape over plug to prevent inadvertent dislodging. Plan to purchase plug guard.</p> <p>Plan to follow up with Immunization Program on data loggers with alarms that could be sent to coordinator and back-up phones.</p>					
Results <ul style="list-style-type: none"> What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.) <p>Late on Monday, I talked with Victor regarding continued use of vaccine. Victor had checked with manufacturers which confirmed that vaccine is acceptable for use. He told me that vaccine could therefore be removed from quarantine. I discussed the entire situation with Susie Supervisor and Dr. Director (clinic medical director) who agreed that we could put vaccine back in use.</p>					

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