Vaccine Storage and Handling
Sharon Roy, MD, MPH

Storage and Handling Mishap #1

- During a Christmas holiday, a clinic closed for a week
- The clinic employee in charge of vaccines placed all of the clinics vaccines in the freezer for “safe keeping”
- When the clinic re-opened, they contacted the State health department for advice on how long to defrost the vaccines before using
- $50,000 of vaccines were lost

Storage and Handling Mishap #2

- A clinic discovered vaccines had been exposed to freezing temperatures potentially affecting 3,400 patients, half of them children

- An estimated $300,000 was spent in response including revaccination.

Storage and Handling Mishap #3

- A refrigerator at a large State vaccine distribution center set off the temperature alarm
- 53 minutes later the security organization contacted the designated public health employee

Storage and Handling Mishap #3

- PH employee arrived at the distribution center 44 minutes after being contacted. On his arrival, the temperature was -10° C
- 63,000 doses of Td valued at $486,423 were lost

Vaccine Storage and Handling

- Vaccines are fragile and must be kept at recommended temperatures at all times
- Vaccines are expensive
- It is better to NOT VACCINATE than to administer a dose of vaccine that has been mishandled

The Effect of "Thermotrauma" on Vaccines

- Live vaccines
  - Tolerate freezing
  - Live viruses deteriorate rapidly after removal from refrigeration
- Inactivated vaccines
  - Inactivated by freezing
  - Tolerate short times out of refrigeration

Storage and Handling Take-Home Messages

- Colder is NOT better for inactivated vaccines
- Out of range temperature readings require IMMEDIATE action
- It is estimated that >$100 million worth of vaccine is exposed to freezing temperatures each year in the United States

The "Cold Chain"

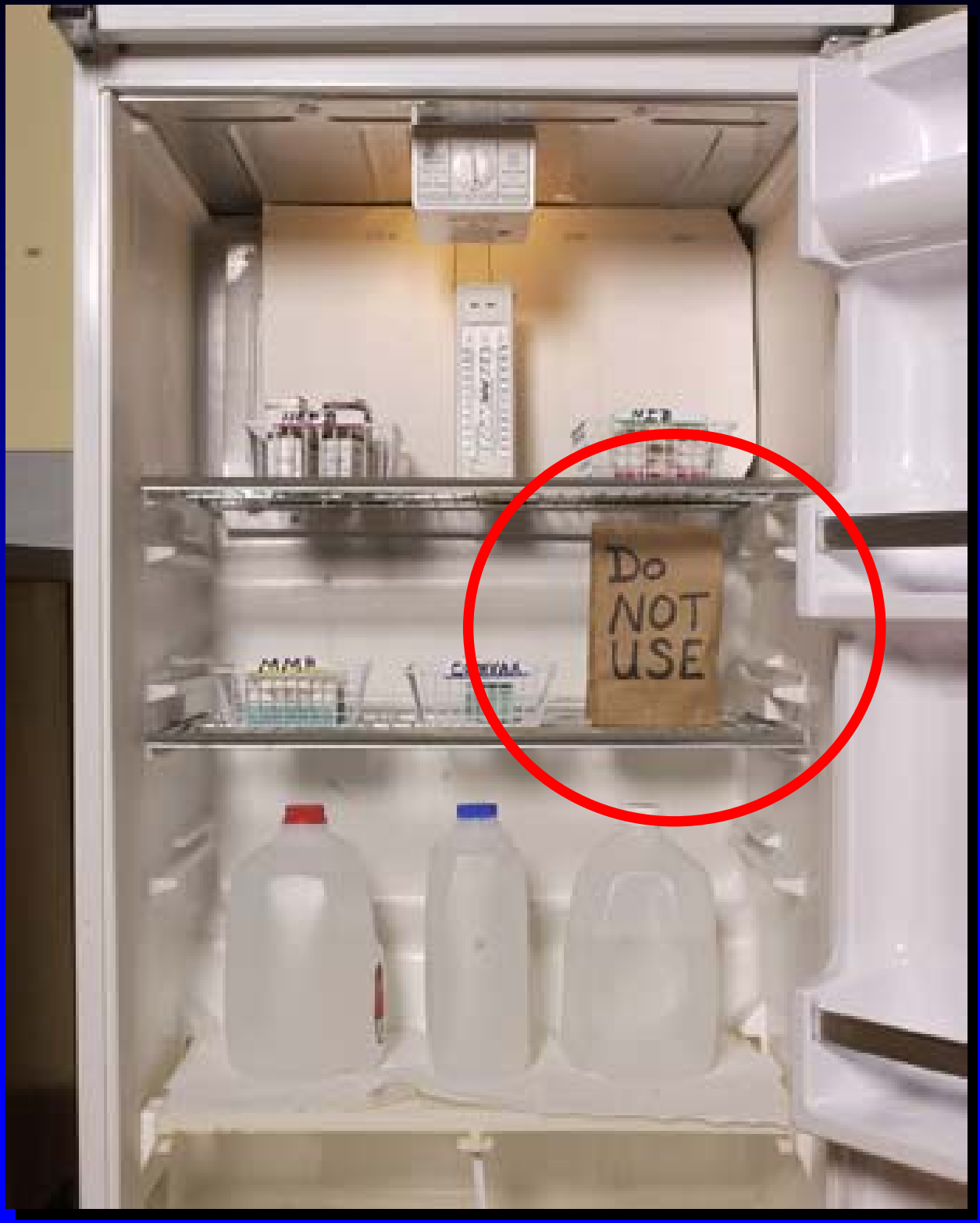
- Vaccines must be stored properly from the time they are manufactured until they are administered to your patients
  - Manufacturer to distributor
  - Distributor to office
  - Office to patient

Vaccine Storage and Handling Guidelines

- Develop and maintain detailed written S&H protocol
- Assign S & H responsibilities to 1 person
- Designate a back-up person
- Provide training on vaccine storage and handling

Vaccine Shipments

- Examine shipment on arrival
- Check contents against packing slip
- Check vaccine expiration dates
- Examine contents for damage
- Assure shipping time <48 hours


Do
NOT
USE

Vaccine Inventory Log

- Name of each vaccine
- Number of doses of each vaccine received
- Date received
- Condition upon arrival
- Vaccine manufacturers
- Lot numbers
- Expiration date for each vaccine

Vaccine Storage Requirements

- Maintain required temperature range year-round
- Large enough to hold year's largest inventory
- Dedicated to biologics

Vaccine Storage Requirements

Recommended Temperatures

Refrigerator	Freezer (varicella & LAIV)
35º - 46ºF	≤ +5ºF
OR	OR
2º - 8ºC	≤ -15ºC
Average 40ºF (5ºC)	

Temperature Monitoring

Protect Your Vaccines: Check Temperatures Twice a Day! Mo./Yr.:_____ Days 1–15

Instructions: Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. **Store the vaccine** under proper conditions as quickly as possible, 2. **Call the vaccine manufacturer**(s) to determine whether the potency of the vaccine(s) has been affected, 3. **Call the immunization program at your local health department** for further assistance: (_____) _____, and 4. **Document the action taken** on the reverse side of this log.

Day of Month		1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Exact Time																															
°F Temp		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
	≥49°																														
	48°																														
	47°																														
	46°																														
	45°																														
	44°																														
Refrigerator temperature	43°																														
	42°																														
	41°																														
	40°																														
	39°																														
	38°																														
	37°																														
	36°																														
	35°																														
	34°																														
	33°																														
	32°																														
	31°																														
	30°																														
	29°																														
	≤28°																														
Freezer temp	≥8°																														
	7°																														
	6°																														
	5°																														
	4°																														
	≤3°																														
Room temp																															
Staff Initials																															

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health

www.immunize.org/catg.d/p3039.pdf • Item # P3039 (7/02)

Temperature Monitoring

Protect Your Vaccines: Check Temperatures Twice a Day! Mo./Yr.:_____ Days 1–15

Instructions: Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. **Store the vaccine** under proper conditions as quickly as possible, 2. **Call the vaccine manufacturer**(s) to determine whether the potency of the vaccine(s) has been affected, 3. **Call the immunization program at your local health department** for further assistance: (_____) _____, and 4. **Document the action taken** on the reverse side of this log.

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Exact Time																														
°F Temp	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
≥49°																														
48°																														
47°																														
46°																														
45°																														
44°																														
43°																														
42°																														
41°																														
40°																														
39°																														
38°																														
37°																														
36°																														
35°																														
34°																														
33°																														
32°																														
31°																														
30°																														
29°																														
≤28°																														
≥8°																														
7°																														
6°																														
5°																														
4°																														
≤3°																														
Room temp																														
Staff Initials																														

Refrigerator temperature

Freezer temp

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health

www.immunize.org/catg.d/p3039.pdf • Item # P3039 (7/02)

Immunization Action Coalition • 1573 Selby Ave., Ste. 234 • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org • admin@immunize.org

Temperature Monitoring

Protect Your Vaccines: Check Temperatures Twice a Day! Mo./Yr.:_____ Days 1–15

Instructions: Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. **Store the vaccine** under proper conditions as quickly as possible, 2. **Call the vaccine manufacturer**(s) to determine whether the potency of the vaccine(s) has been affected, 3. **Call the immunization program at your local health department** for further assistance: (_____) _____, and 4. **Document the action taken** on the reverse side of this log.

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Exact Time																														
°F Temp	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
≥49°																														
48°																														
47°																														
46°																														
45°																														
44°																														
43°																														
42°																														
41°																														
40°																														
39°																														
38°																														
37°																														
36°																														
35°																														
34°																														
33°																														
32°																														
31°																														
30°																														
29°																														
≤28°																														
≥8°																														
7°																														
6°																														
5°																														
4°																														
≤3°																														
Room temp																														
Staff Initials																														

Refrigerator temperature

Freezer temp

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health

www.immunize.org/catg.d/p3039.pdf • Item # P3039 (7/02)

Temperature Monitoring

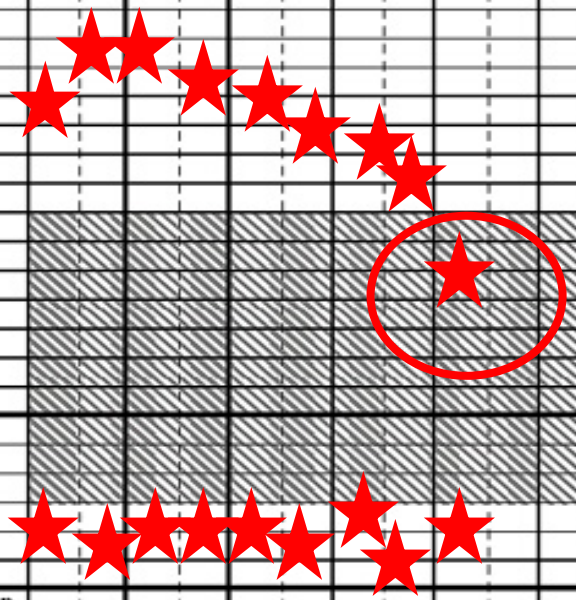
Protect Your Vaccines: Check Temperatures Twice a Day! Mo./Yr.:_____ Days 1–15

Instructions: Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. **Store the vaccine** under proper conditions as quickly as possible, 2. **Call the vaccine manufacturer**(s) to determine whether the potency of the vaccine(s) has been affected, 3. **Call the immunization program at your local health department** for further assistance: (_____) _____, and 4. **Document the action taken** on the reverse side of this log.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Exact Time															
°F Temp	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
≥49°															
48°															
47°															
46°															
45°															
44°															
43°															
42°															
41°															
40°															
39°															
38°															
37°															
36°															
35°															
34°															
33°															
32°															
31°															
30°															
29°															
≤28°															
≥8°															
7°															
6°															
5°															
4°															
≤3°															
Room temp															
Staff Initials															

Refrigerator temperature

Freezer temp



IMMEDIATE ACTION!

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health

www.immunize.org/catg.d/p3039.pdf • Item # P3039 (7/02)

Thermometer Placement

Refrigerator

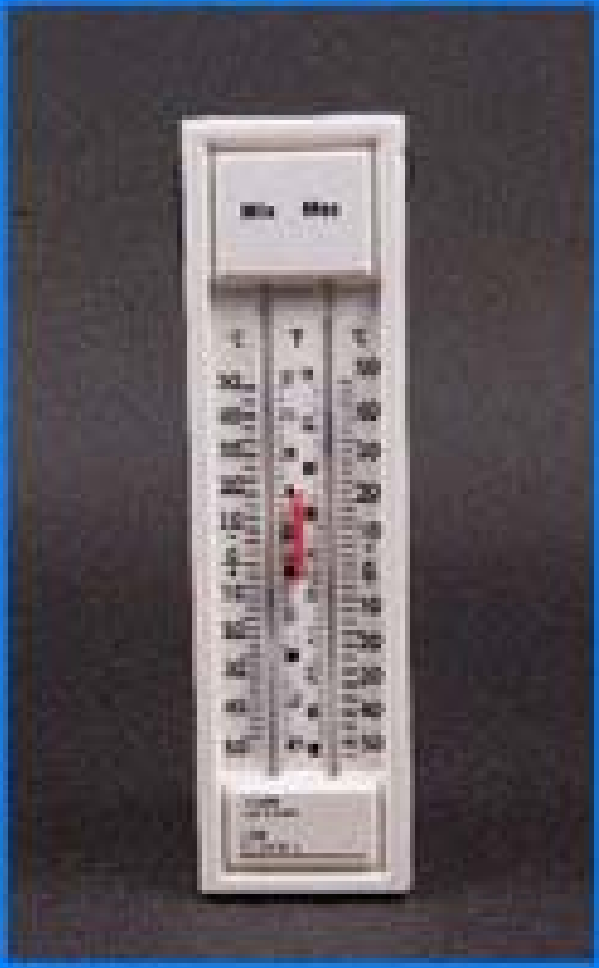
Freezer

Certified Calibrated Thermometers

Bio-safe liquid

Continuous graphic

Minimum-maximum



Certified Calibrated Thermometers

1365

CERTIFICATE of CONFORMANCE & ACCURACY

This thermometer identified by Serial No. 12508
was compared with a Standard calibrated at the National Institute of Standards and Technology (NIST), formerly the National Bureau of Standards (NBS); and was found to be within one scale division. The indications of this thermometer are traceable to N.I.S.T.

The standard Serial No. is 59001
The NIST Identification No. is 119016

TEST DATE APR 23 2003

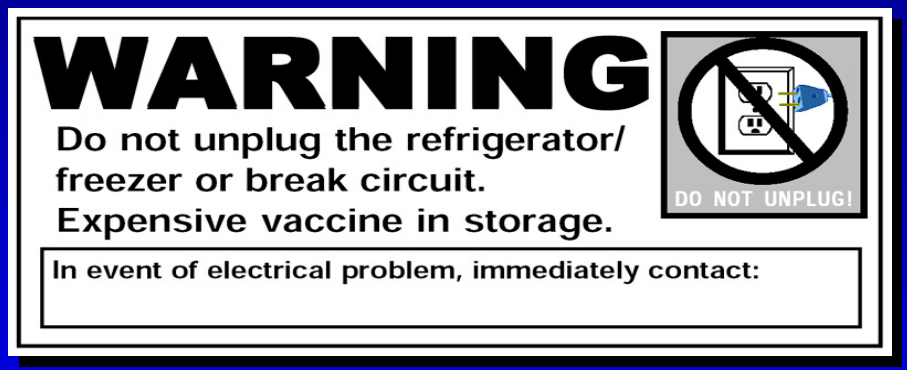
EVER-READY THERMOMETER CO.
QUALITY SINCE 1942

Clifton Thomas, *Quality Control Supervisor*
Ever-Ready Thermometer Co., Inc.
228 Lackawanna Avenue
West Paterson, NJ 07424
Phone 973/812-7474 Fax 973/812-7475

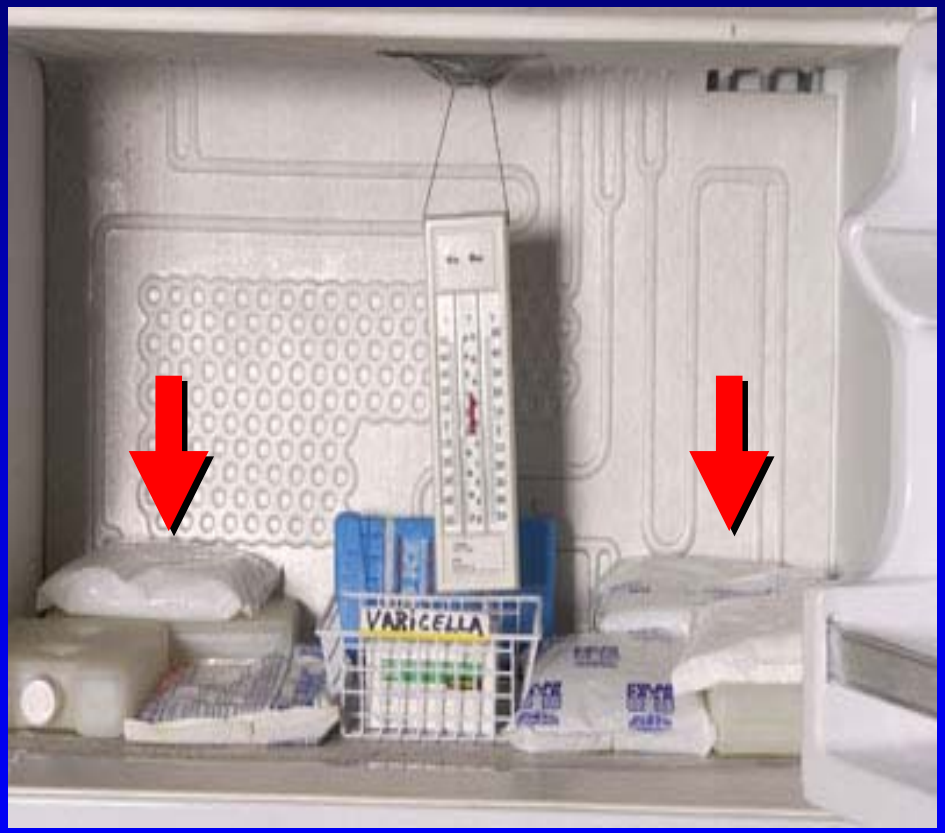
THE VALIDITY OF THIS CERTIFICATE & INSTRUMENT IS ONE YEAR

Preventive Measures

- Use a plug guard or safety-lock plug
- Post a warning sign at the plug and on the refrigerator
- Label fuses and circuit breakers
- Install a temperature alarm



Temperature Control



Refrigerator **Freezer**

Vaccine Storage After Opening or Reconstitution

- Multidose vials
  - –contain a bacteriostatic agent
  - –can be used until the expiration date unless contaminated

Vaccine Storage After Opening or Reconstitution

- Single dose vials
  - do NOT contain a bacteriostatic agent
  - once opened use or discard at the end of the clinic day
- Reconstituted vials
  - Consult package insert for life of vaccine once reconstituted

"Prefilling" Syringes

- Practice strongly discouraged by the National Immunization Program
- May result in vaccine administration errors, vaccine wastage, possible bacterial growth

"Prefilling" Syringes

- Consider using manufacturer-supplied prefilled syringes for large immunization clinics (e.g., annual influenza clinics)

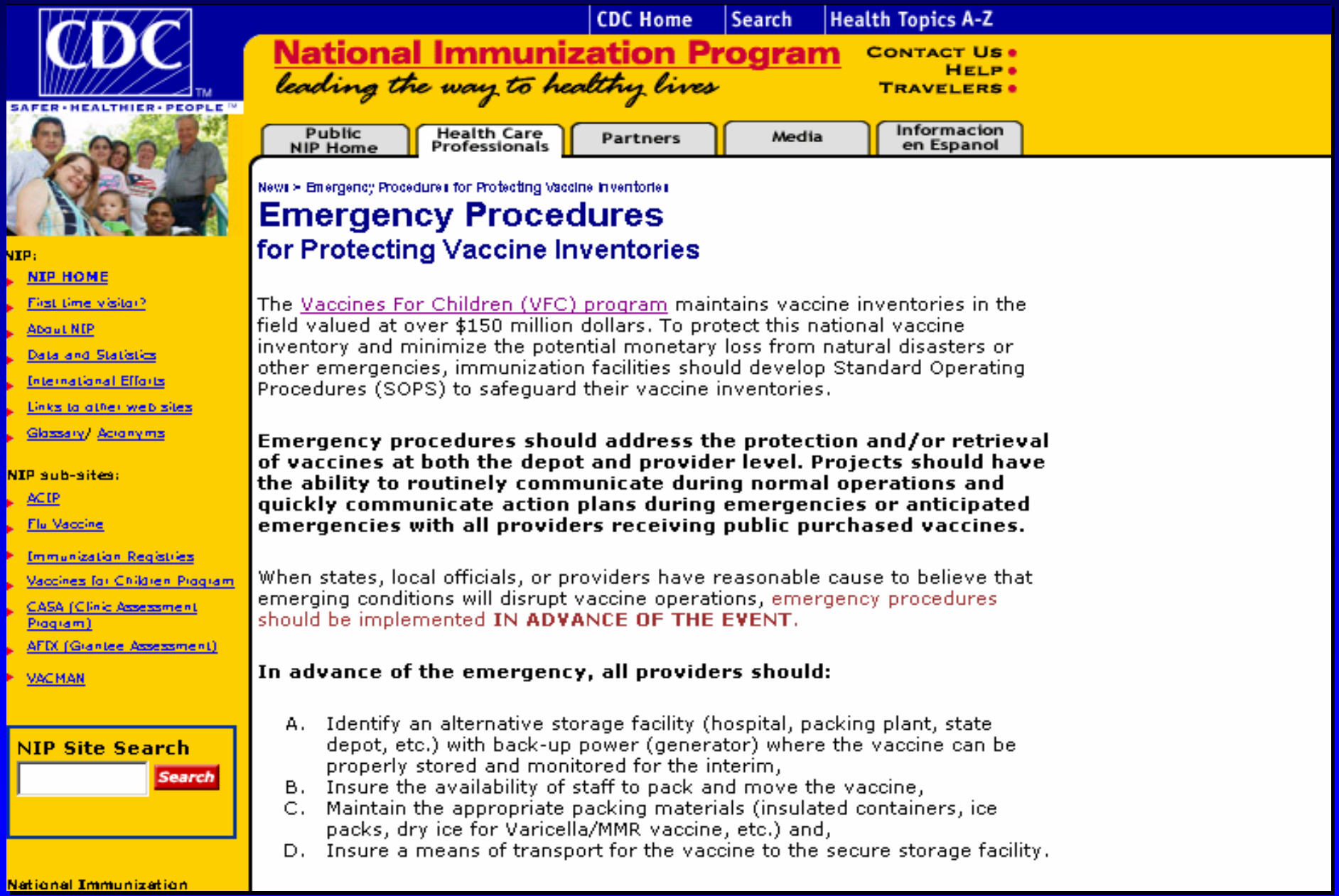
- Syringes other than those filled by manufacturer should be discarded at end of clinic day

Vaccine Inventory Control

- Conduct a monthly vaccine inventory
- Avoid stocking excessive vaccine supplies
- Monitor expiration dates and rotate stock to avoid waste
- Never use expired vaccine or diluent
- Limit access to authorized personnel

Emergency Preparedness

www.cdc.gov/nip/news/vacc_weather_emerg.htm



CDC Home | Search | Health Topics A-Z

CDC
SAFER·HEALTHIER·PEOPLE™

National Immunization Program
leading the way to healthy lives

CONTACT US • HELP • TRAVELERS •

Public NIP Home | Health Care Professionals | Partners | Media | Informacion en Espanol

NIP:
- NIP HOME
- First time visitor?
- About NIP
- Data and Statistics
- International Efforts
- Links to other web sites
- Glossary/ Acronyms

NIP sub-sites:
- ACIP
- Flu Vaccine
- Immunization Registries
- Vaccines for Children Program
- CASA (Clinic Assessment Program)
- AFIX (Grantee Assessment)
- VACMAN

NIP Site Search
Search

National Immunization

News > Emergency Procedures for Protecting Vaccine Inventories

Emergency Procedures
for Protecting Vaccine Inventories

The Vaccines For Children (VFC) program maintains vaccine inventories in the field valued at over $150 million dollars. To protect this national vaccine inventory and minimize the potential monetary loss from natural disasters or other emergencies, immunization facilities should develop Standard Operating Procedures (SOPS) to safeguard their vaccine inventories.

Emergency procedures should address the protection and/or retrieval of vaccines at both the depot and provider level. Projects should have the ability to routinely communicate during normal operations and quickly communicate action plans during emergencies or anticipated emergencies with all providers receiving public purchased vaccines.

When states, local officials, or providers have reasonable cause to believe that emerging conditions will disrupt vaccine operations, emergency procedures should be implemented **IN ADVANCE OF THE EVENT.**

In advance of the emergency, all providers should:

A. Identify an alternative storage facility (hospital, packing plant, state depot, etc.) with back-up power (generator) where the vaccine can be properly stored and monitored for the interim,
B. Insure the availability of staff to pack and move the vaccine,
C. Maintain the appropriate packing materials (insulated containers, ice packs, dry ice for Varicella/MMR vaccine, etc.) and,
D. Insure a means of transport for the vaccine to the secure storage facility.

Vaccine Storage & Handling Resources

- National Immunization Program (NIP)

www.cdc.gov/nip/menus/vaccines.htm#Storage

- Immunization Action Coalition (IAC)

www.immunize.org

www.immunize.org/nslt.d/n17/catalg1.htm

Checklist for Safe Vaccine Handling and Storage

Here are the 20 most important things you can do to safeguard your vaccine supply. Are you doing them all? Reviewing this list can help you improve your clinic's vaccine management practices.

Yes	No		
____	____	1.	We have a designated person in charge of the handling and storage of our vaccines.
____	____	2.	We have a back-up person in charge of the handling and storage of our vaccines.
____	____	3.	A vaccine inventory log is maintained that documents:
			____ Vaccine name and number of doses received
			____ Date the vaccine was received
			____ Arrival condition of vaccine
			____ Vaccine manufacturer and lot number
			____ Vaccine expiration date
____	____	4.	Our refrigerator for vaccines is either household-style or commercial-style, NOT dormitory-style. The freezer compartment has a separate door.
____	____	5.	We do NOT store any food or drink in the refrigerator or freezer.
____	____	6.	We store vaccines in the middle of the refrigerator or freezer, and NOT in the door.
____	____	7.	We stock and rotate our vaccine supply so that the newest vaccine of each type (with the longest expiration date) is placed behind the vaccine with the shortest expiration date.
____	____	8.	We check vaccine expiration dates and we first use those that will expire soonest.
____	____	9.	We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.
____	____	10.	We always keep a thermometer in the refrigerator.
____	____	11.	The temperature in the refrigerator is maintained at 35–46°F (2–8°C).
____	____	12.	We keep extra containers of water in the refrigerator to help maintain cold temperatures.
____	____	13.	We always keep a thermometer in the freezer.
____	____	14.	The temperature in the freezer is maintained at +5°F (-15°C) or colder.
____	____	15.	We keep ice packs and other ice-filled containers in the freezer to help maintain cold temperatures.
____	____	16.	We post a temperature log on the refrigerator door on which we record the refrigerator and freezer temperatures twice a day—first thing in the morning and at clinic closing time—and we know whom to call if the temperature goes out of range.
____	____	17.	We have a "Do Not Unplug" sign next to the refrigerator's electrical outlet.
____	____	18.	In the event of a refrigerator failure, we take the following steps:
			____ We assure that the vaccines are placed in a location with adequate refrigeration.
			____ We mark exposed vaccines and separate them from undamaged vaccines.
			____ We note the refrigerator or freezer temperature and contact the manufacturer or state health department to determine how to handle the affected vaccines.
			____ We follow the manufacturer's or health department's instructions as to whether the affected vaccines can be used, and, if so, we mark the vials with the revised expiration date provided by the manufacturer or health department.
____	____	19.	We have obtained a detailed written policy for general and emergency vaccine management from our local or state health department.
____	____	20.	If all above answers are "yes," we are patting ourselves on the back. If not, we have assigned someone to implement needed changes!

Item #P5115 (11/01)

Immunization Action Coalition • 1573 Selby Avenue • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org

www.immunize.org/nslt.d/n17/catalg1.htm

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

The following are frequently reported errors in vaccine storage and handling. Some of these errors are much more serious than others, but none of them should occur. Be sure your clinic or practice is not making errors such as these.

Error #1: Designating only one person in the office to be responsible for storage and handling of vaccines, instead of a minimum of two.

It's important to train at least one back-up person to learn proper storage and handling of vaccines. The back-up person should be familiar with all aspects of vaccine storage and handling, including knowing how to handle vaccines when they arrive, how to properly record refrigerator and freezer temperatures, and what to do in case of an equipment problem or power outage.

Error #2: Recording temperatures only once per day.

Temperatures fluctuate throughout the day. Temperatures in the refrigerator and freezer should be checked at the beginning and end of the day to determine if the unit is getting too cold or too warm. Ideally, you should have continuous thermometers that measure and record temperatures all day and all night. Also: expensive alternative is to purchase maximum/minimum thermometers. It's also a good idea to record the room temperature on your temperature log in case there is a problem with the refrigerator or freezer temperature. This information may be helpful to the vaccine company's telephone consultant in ascertaining whether your vaccine can still be used.

Error #3: Recording temperatures for only the refrigerator or freezer.

If your facility administers varicella vaccine, you should have thermometers in both the refrigerator and the freezer. Rather than buying cheap thermometers that may not accurately measure the temperature, buy quality thermometers that will last for years.

Error #4: Documenting out-of-range temperatures on vaccine temperature logs and not taking action.

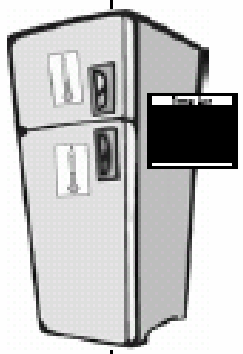
Documenting temperatures is not enough. Acting on the information is even more important! So, what should you do? Notify your supervisor whenever you have an out-of-range temperature. Safeguard your vaccines by moving them to another location and then determine if they are still viable. Check the condition of the unit for problems. Are the seals tight? Is there excessive lint or dust on the coils? After you have made the adjustment, document the date, time, temperature, what the problem was, the action you took, and the results of this action. Recheck the temperature every two hours. Call maintenance or a repair person if the temperature is still out of range.

Error #5: Throwing away temperature logs at the end of every month.

It's important that you keep your temperature logs for at least three years. As the refrigerator ages, you can track recurring problems. If temperatures have been documented out of range, you can determine how long this has been happening and take appropriate action. It's also a great way to lobby for a new refrigerator.

Error #6: Storing vaccine in the wrong part of the refrigerator (e.g., vegetable bin, plastic container, the door, bottom, or near the cold air outlet from the freezer).

The temperatures in these areas may differ significantly from the temperature in the body of the refrigerator. Always place vaccines on the shelves in open, labeled containers, so that air can circulate around the vaccines.



Error #7: Storing varicella vaccine in a dorm-style refrigerator.

Varicella must be stored in a freezer that has its own external door separate from the refrigerator. No matter how hard you try to adjust the temperature to +5°F in a dorm-style refrigerator/freezer, you won't be able to reach this low temperature in the freezer, and you'll probably freeze the rest of your vaccines in the refrigerator!

Error #8: Inadvertently leaving the refrigerator or freezer door open or having inadequate seals.

Remind staff to close the unit doors tightly each time they open them. Also, check the seals on the doors on a regular schedule, and if there is any indication the door seal may be cracked or not sealing properly, have it replaced. The cost of replacing a seal is much less than replacing a box of pneumococcal conjugate or varicella vaccine.

Error #9: Discarding multi-dose vials 30 days after they are opened.

Don't discard your vaccines prematurely. Almost all multi-dose vials of vaccine have preservatives in them and can be used until the expiration date on the vial unless there is visible contamination. However, you must discard multi-dose vials of reconstituted vaccine (e.g., meningococcal, yellow fever) if they are not used within a defined period after reconstitution. Refer to the vaccine package inserts for additional information.

Error #10: Not having emergency plans for a power outage or natural disaster.

Every clinic should have a written Disaster Recovery Plan that identifies a refrigerator with a back-up generator in which to store vaccine in the event of a power outage or natural disaster. Consider contacting a local hospital or similar facility to be your back-up location if you should need it.

Immunization Action Coalition • 1573 Selby Avenue • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org

Vaccine Storage & Handling Resources

National Immunization Program

- Hotline (800) 232-2522
- Email nipinfo@cdc.gov
- Website www.cdc.gov/nip*

*download or order ACIP statements online from the NIP website