vaccine storage and handling

Don't be a weak link in the [cold] chain

Vaccine storage and handling: What's the big deal?

Barriers to immunization best practice:

- Medical clinics are busy places; vaccinations are only a small part of the job.
- Difficult getting upper management support for the time and resources required to do the work.
- Rapid staff turnover leads to inadequate (on nonexistent) training.
- Federal and State requirements feel excessive and unrealistic.

Are Doctors Improperly Storing Vaccines?

June 6, 2012

By KIM CAROLLO via **NIGHTLINE**

Findings from the 2012 OIG audit

- VFC vaccines stored by 76 % (34 of 45) of the selected providers were exposed to inappropriate temps for at least 5 cumulative hours during that (2-week) period.

- Thirteen providers stored expired vaccines together with non-expired vaccines.

- Selected providers generally did not meet vaccine management requirements or maintain required documentation.

- None of the 45 selected providers managed VFC vaccines according to all vaccine management requirements.

Source: http://oig.hhs.gov/oei/reports/oei-04-10-00430.pdf

Vaccines are sensitive

Live vaccines are sensitive to heat. MMRV, varicella, and zoster vaccines must be stored in a continuously frozen state in a freezer at 5°F (-15°C) or colder. MMR can be stored in either the refrigerator or freezer.

Inactivated vaccines are sensitive to both heat and freezing. They should be stored in a refrigerator at 36° to 46°F (2° to 8°C).

Some vaccines are sensitive to light, which causes loss of potency. HPV, MMR, MMRV rotavirus, varicella and zoster must be protected from light at all times. Store vaccines in their boxes and only pull from one box at a time.

Vaccines are expensive

GARDASIL

HPV $193.63

ProQuad (Measles, Mumps, Rubella and Varicella Virus Vaccine Live)

MMRV $191.12

Prevnar 13

PCV 13 $159.58

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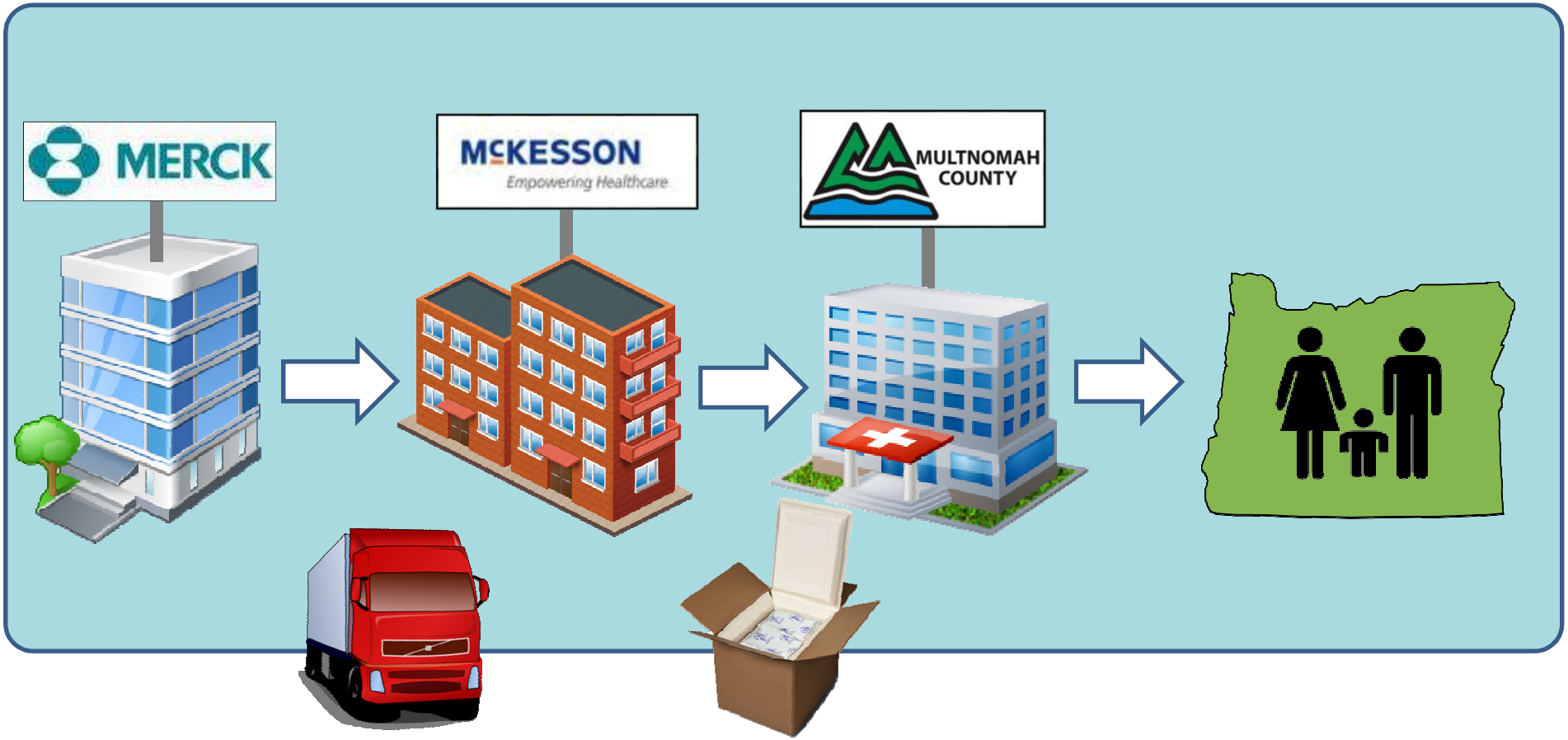
The vaccine cold chain



Continuous tracking data loggers

Data logger options

Pen and paper

Stand-alone

Wireless/Cloud

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Warning from far and near

Phone-based

Wireless and web-based

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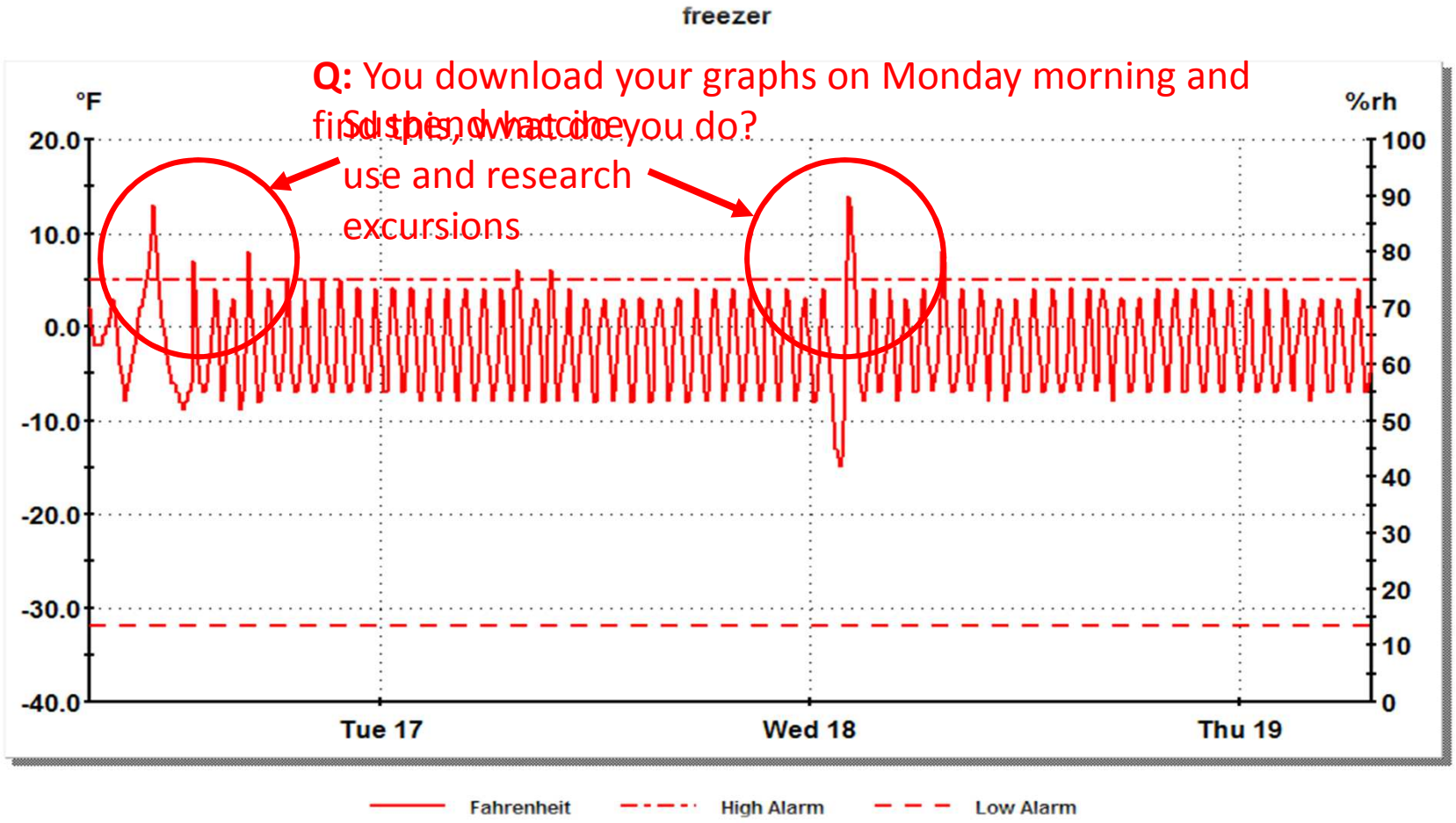
Logger requirements and recommendations

- Use a calibrated logger in every vaccine storage unit.
- Maintain at least one calibrated back-up logger at every site.
- It's recommended that your loggers use an external probe in buffered material (e.g. glycol, glycerin, glass beads).

Download and review digital logs weekly



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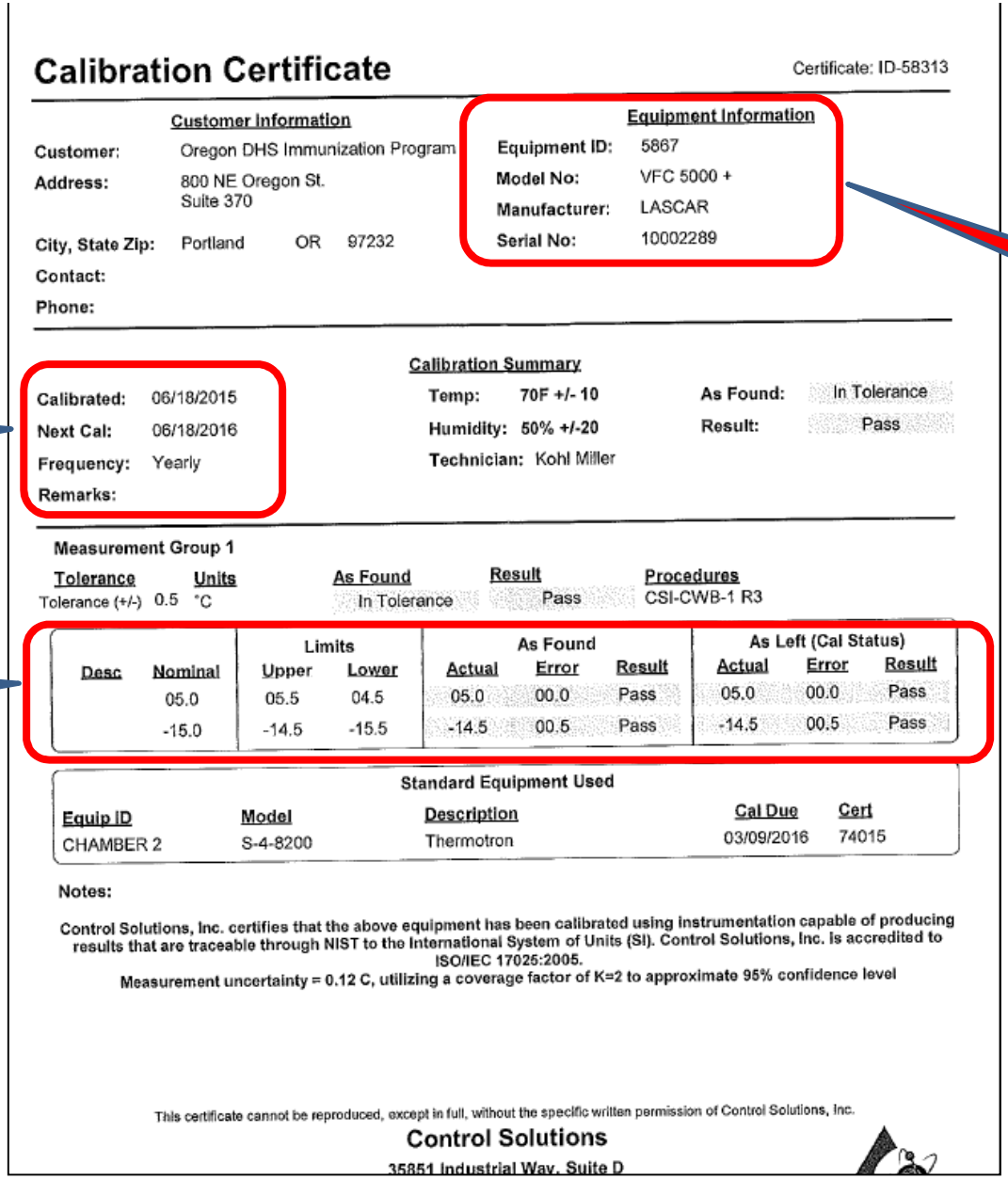
Certificate of calibration

Calibration requirements

According to the CDC, “Thermometer calibration must be tested annually (or according to the manufacturer’s recommendation).”

At a minimum, the calibration certificate must include:

- ❑ Model/Device Name or Number
- ❑ Serial Number
- ❑ Date of Calibration (Report or Issue Date)
- ❑ Instruments Passed Testing (Instrument is within tolerance)



Calibration Certificate

Certificate: ID-58313

Customer Information

Customer: Oregon DHS Immunization Program
Address: 800 NE Oregon St. Suite 370
City, State Zip: Portland OR 97232
Contact:
Phone:

Equipment Information

Equipment ID: 5867
Model No: VFC 5000 +
Manufacturer: LASCAR
Serial No: 10002289

Calibration Summary

Calibrated: 06/18/2015
Next Cal: 06/18/2016
Frequency: Yearly
Remarks:

Temp: 70F +/- 10
Humidity: 50% +/-20
Technician: Kohl Miller

As Found: In Tolerance
Result: Pass

Measurement Group 1

Tolerance	Units	As Found	Result	Procedures
Tolerance (+/-) 0.5	°C	In Tolerance	Pass	CSI-CWB-1 R3

		Limits		As Found			As Left (Cal Status)		
Desc	Nominal	Upper	Lower	Actual	Error	Result	Actual	Error	Result
	05.0	05.5	04.5	05.0	00.0	Pass	05.0	00.0	Pass
	-15.0	-14.5	-15.5	-14.5	00.5	Pass	-14.5	00.5	Pass

Standard Equipment Used

Equip ID	Model	Description	Cal Due	Cert
CHAMBER 2	S-4-8200	Thermotron	03/09/2016	74015

Notes:

Control Solutions, Inc. certifies that the above equipment has been calibrated using instrumentation capable of producing results that are traceable through NIST to the International System of Units (SI). Control Solutions, Inc. is accredited to ISO/IEC 17025:2005.
Measurement uncertainty = 0.12 C, utilizing a coverage factor of K=2 to approximate 95% confidence level

Control Solutions
35851 Industrial Way, Suite D

Equipment Tested

Date tested and Date Due

Measurement Results

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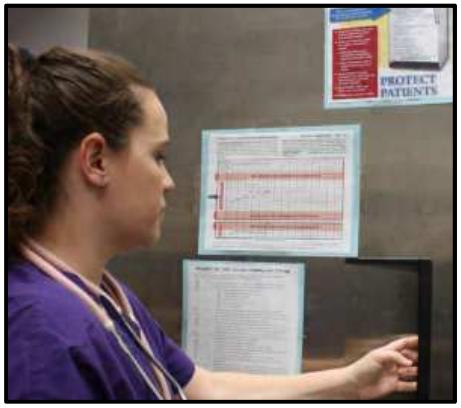
Twice daily temperature logs

Twice daily logs must include:

1) The exact time checked
2) Staff initials
3) Temperature (can use X mark)



Temperature Log for Vaccines (Fahrenheit) Month/Year:_____ Days 1–15

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Room Temp.															
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°															

Too warm*

Take immediate action if temperature is in shaded section*

Too cold*

Aim for 40

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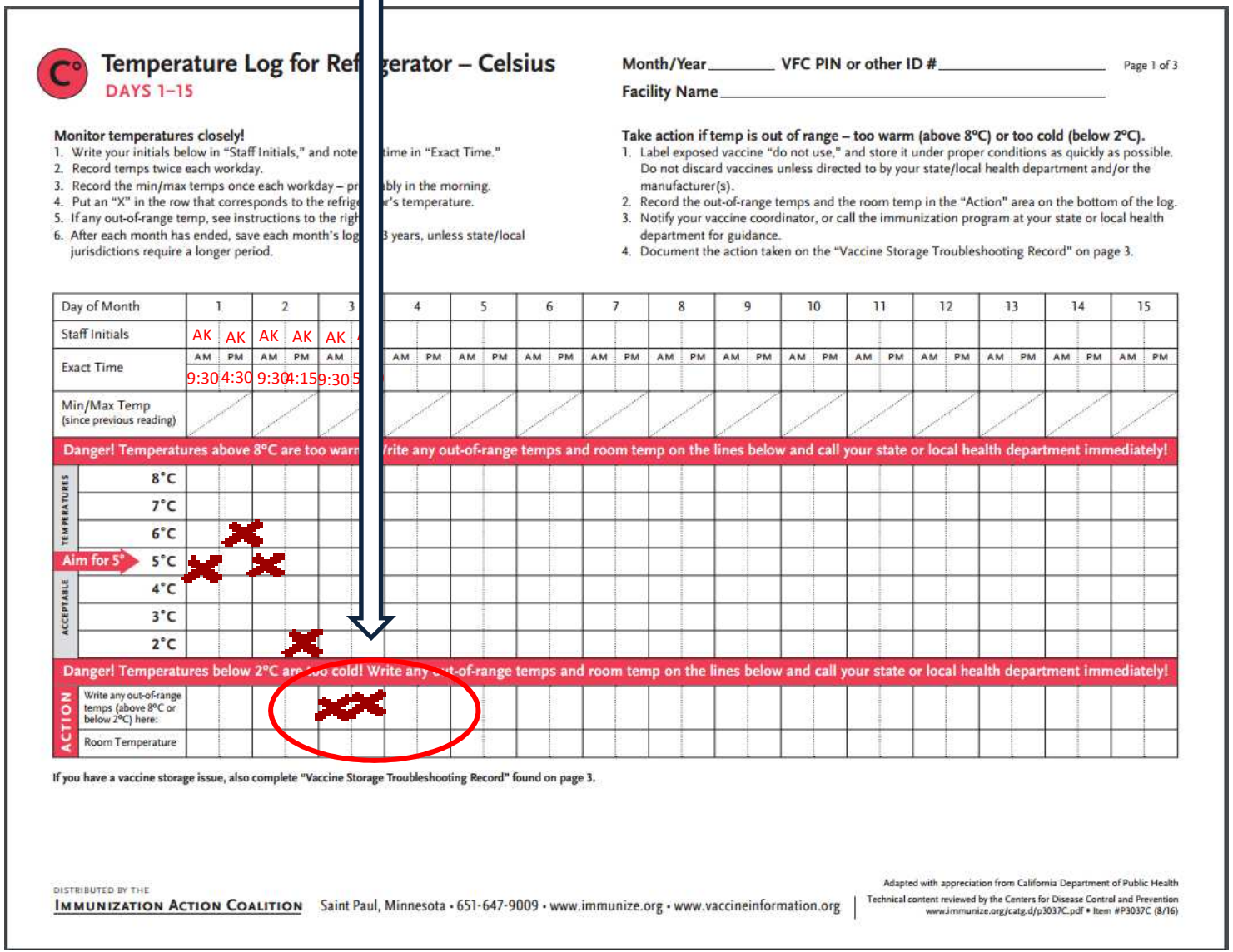
Daily readings

Important: Daily temps must be taken from your calibrated logger (or web-based system), *not* an external display.

Take immediate action if temperatures go out of range



Temperature Log for Ref[illegible]gerator – Celsius

DAYS 1–15

Month/Year_____ VFC PIN or other ID #_____ Page 1 of 3

Facility Name_____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note [illegible]time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday – pr[illegible]ably in the morning.
4. Put an "X" in the row that corresponds to the refrig[illegible]r's temperature.
5. If any out-of-range temp, see instructions to the righ[illegible]
6. After each month has ended, save each month's log[illegible]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).

1. Label exposed vaccine "do not use," and store it 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).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. 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	AK	AK	AK	AK	AK																									
Exact Time	AM	PM	AM	PM	AM		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
	9:30	4:30	9:30	4:15	9:30	5																								
Min/Max Temp (since previous reading)																														

Danger! Temperatures above 8°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!

TEMPERATURES	8°C																													
	7°C																													
	6°C		X																											
Aim for 5°	5°C	X	X																											
ACCEPTABLE	4°C																													
	3°C																													
	2°C			X																										

Danger! Temperatures below 2°C are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!

ACTION																														
	Write any out-of-range temps (above 8°C or below 2°C) here:				X	X																								
	Room Temperature																													

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

DISTRIBUTED BY THE IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

Adapted with appreciation from California Department of Public Health

Technical content reviewed by the Centers for Disease Control and Prevention

www.immunize.org/catg.d/p3037C.pdf • Item #P3037C (8/16)

Implement your vaccine emergency plan, then document the event

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 If multiple, related events occurred, see Description of Event below.	**Storage Unit Temperature** at the time the problem was discovered		**Room Temperature** at the time the problem was discovered	**Person Completing Report**	
Date:	Temp when discovered:		Temp when discovered:	Name:	
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- 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 *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- 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?

Results

- 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.)

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www.immunize.org/catg.d/p3041.pdf • Item #P3041 (8/16)

Vaccine Emergency Plan

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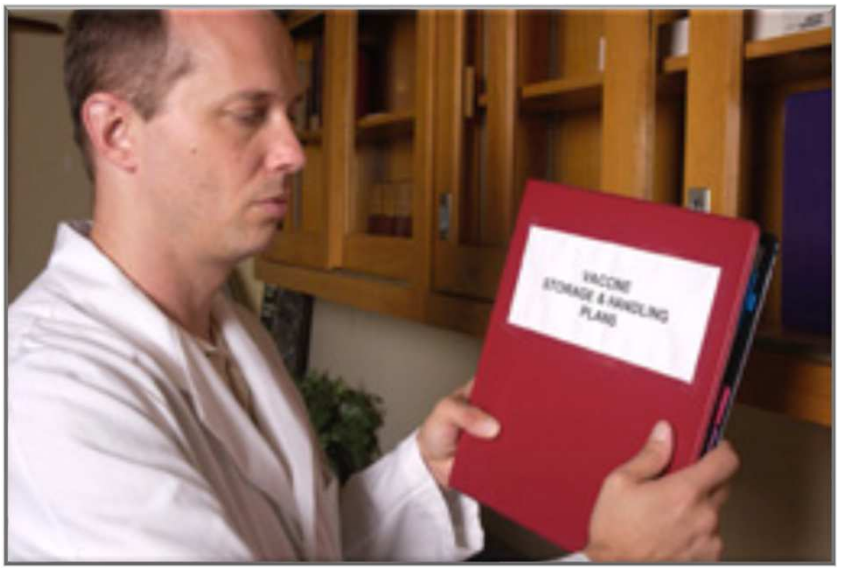
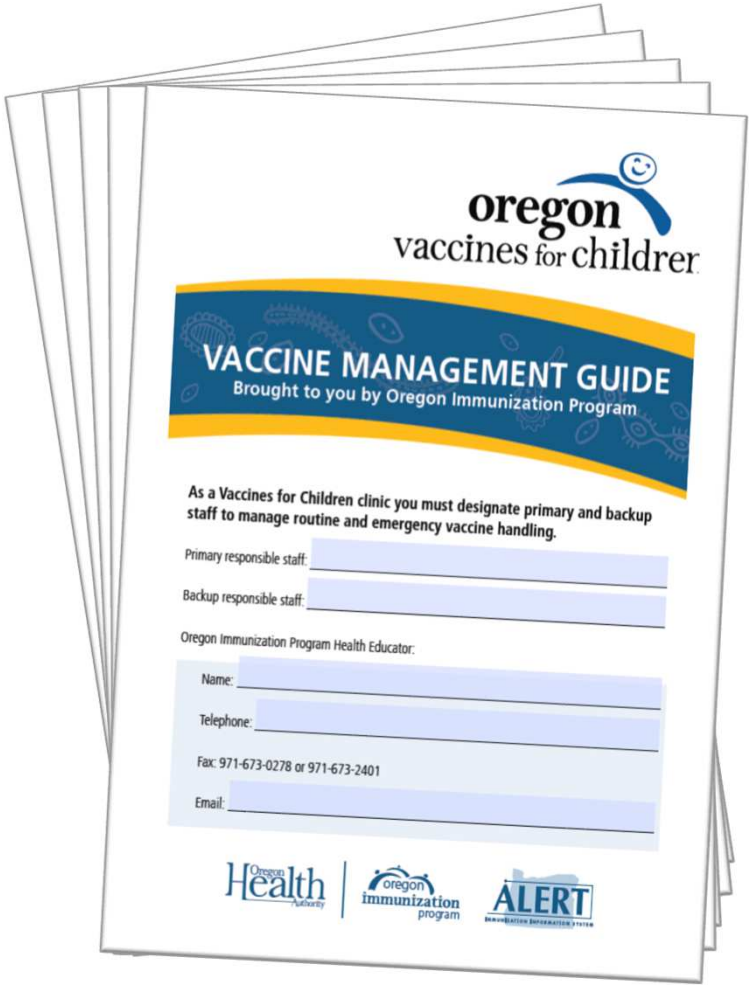
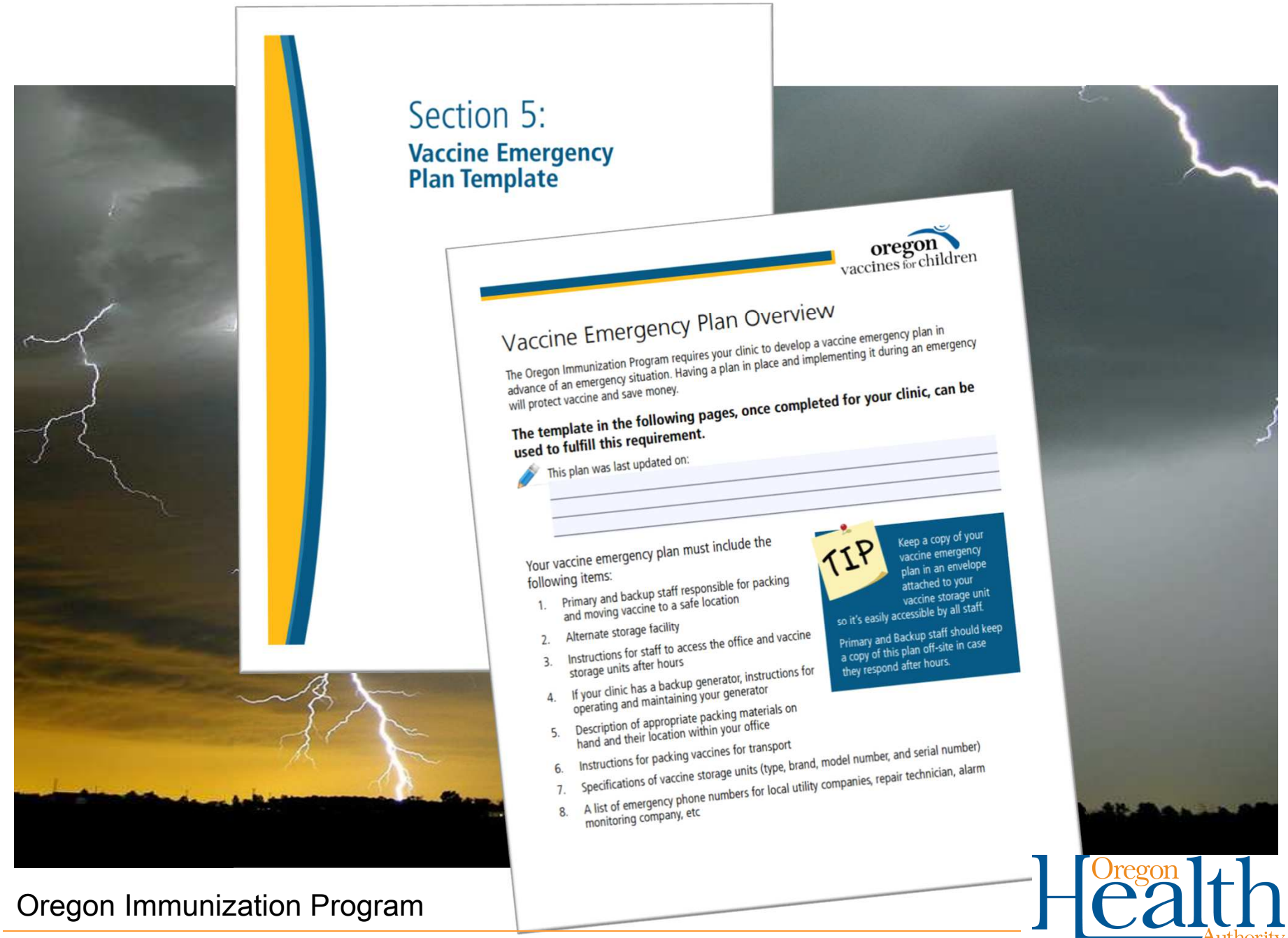
Have a vaccine emergency guide that's updated and accessible



Oregon VFC Vaccine Management Guide



https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/vfc/Documents/VFCVacMgmtGuide.pdf



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Using your vaccine management guide

- Designate a primary and back-up vaccine coordinator.
- The primary vaccine coordinator must review and update the guide annually.
- Have all existing (and new) immunization staff review and sign.
- Keep it in a common area near the vaccine refrigerator and freezer.

Vaccine shipping and transfers

Short dated and expiring vaccine

As stewards of state-supplied vaccine, clinics must make an effort to find homes for vaccines that are soon to expire.

Set ALERT IIS to notify you of expiring vaccines 90 days in advance.

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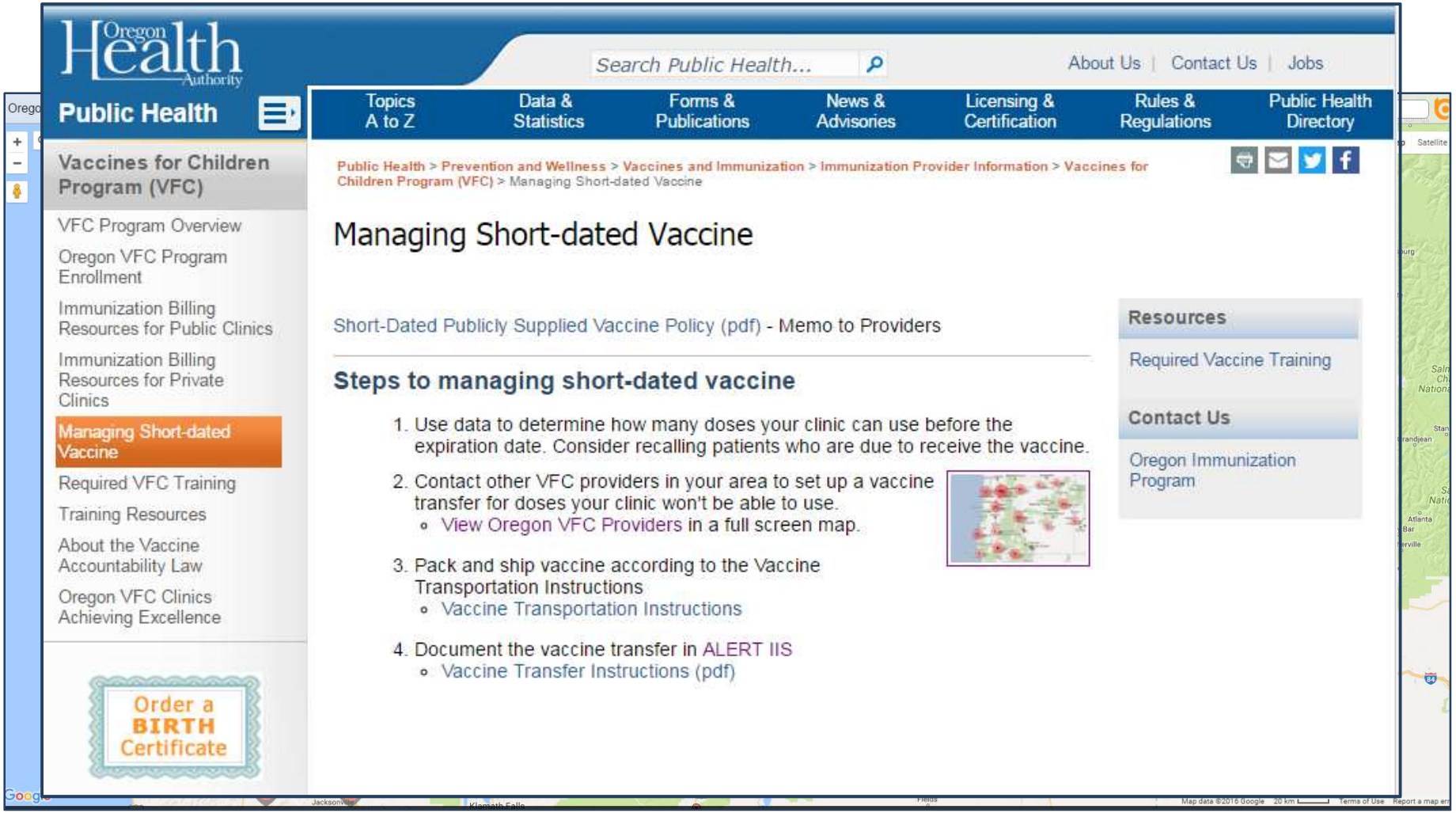
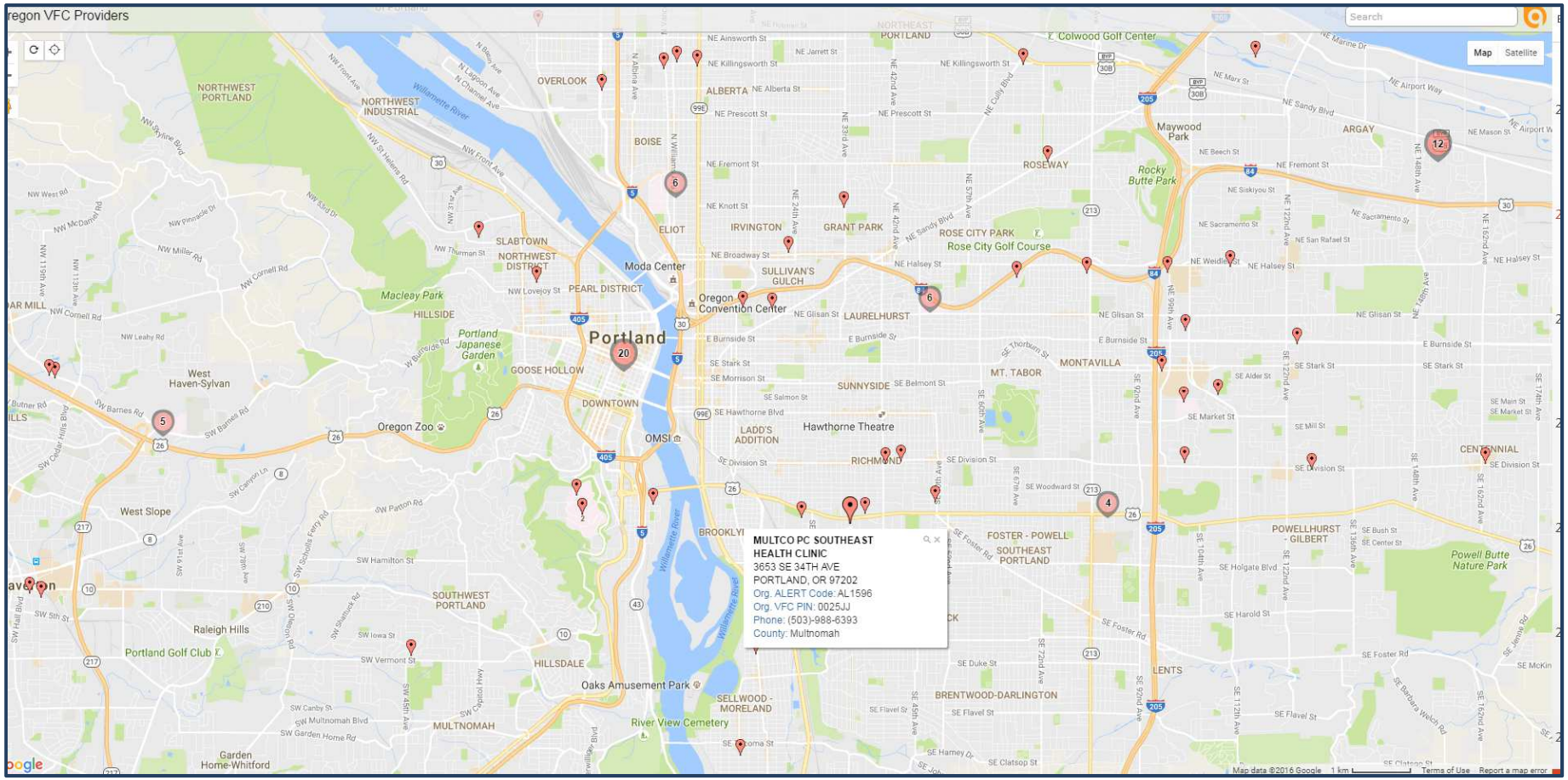
The VFC vaccine transfer map



The VFC vaccine transfer map



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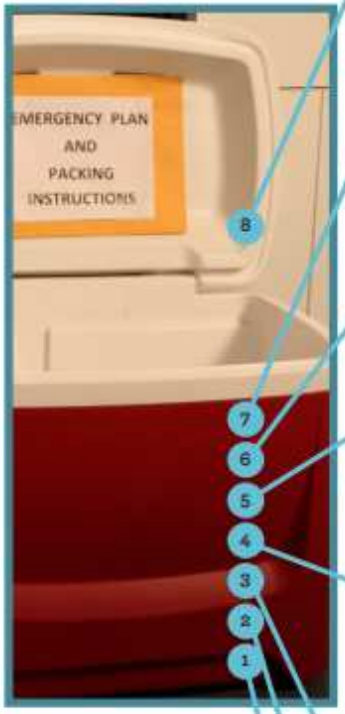
Packing vaccines for transport



8. Temperature Monitoring Device Display (on lid)

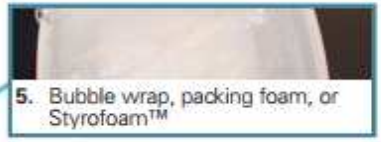
Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.

7. Conditioned Water Bottles

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

6. Cardboard Sheet

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.



5. Bubble wrap, packing foam, or Styrofoam™

Insulating cushioning material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™

4. Vaccines, Diluents, and Temperature Monitoring Device Probe

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.
Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.
Vaccines – Stack boxes of vaccines and diluents on top of insulating material.

3. Bubble wrap, packing foam, or Styrofoam™

Insulating cushioning material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

2. Cardboard Sheet

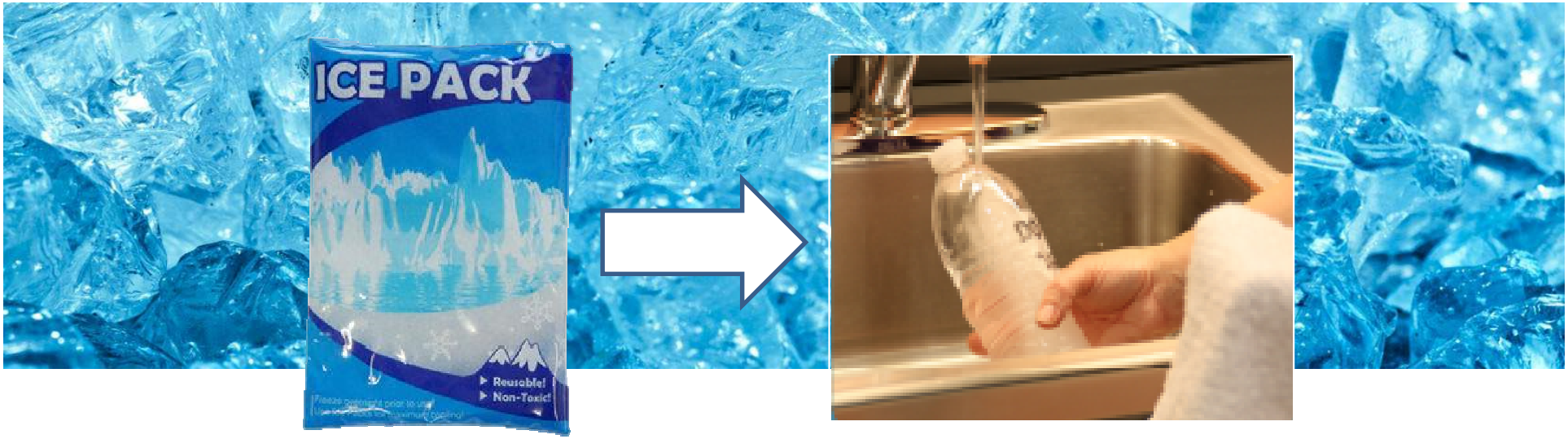
Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

1. Conditioned Water Bottles

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

NOTE:
This pack-out can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

Transitioning to conditioned water bottles



Store water bottles in refrigerator (to improve stability) and freezer (for use during transport).

Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand (this normally takes less than 5 minutes.

Storage options

Refrigerator & freezer options

Consumer-grade

Commercial-grade

Biologic-grade

Biologic-grade sizes

Under counter

Full-size (single)

Full-size (combined)

Storage unit pricing

$150 – 1000 +

$1200 – 7000+

Dorm style refrigerators

Any unit that has a freezer section built into the main storage area.

Not allowed for VFC vaccine storage.

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The fabled lab-grade, dorm-style unit

Compact Refrigerator Freezer Combo

0° F freezer section

24 inch wide footprint and undercounter design

Dual evaporator system cools refrigerator and freezer sections independently

Adjustable glass shelving for varying spacing options

Bottom storage drawer and door shelves

Drawer traps cold air, even while door is open

Automatic internal light when door is opened

Adjustable thermostat for temperature selection

Ideal for storing medications and cold storage vaccines

Two leveling legs for uneven surfaces

Door swing is user-reversible on the basic CT66L model only

Additional PLUS Model Features

Includes traceable thermometer and internal fan cooling

Traceable thermometer digitally displays current, high, and low temperatures

Internal fan with gel packs evenly distributes cold air throughout interior

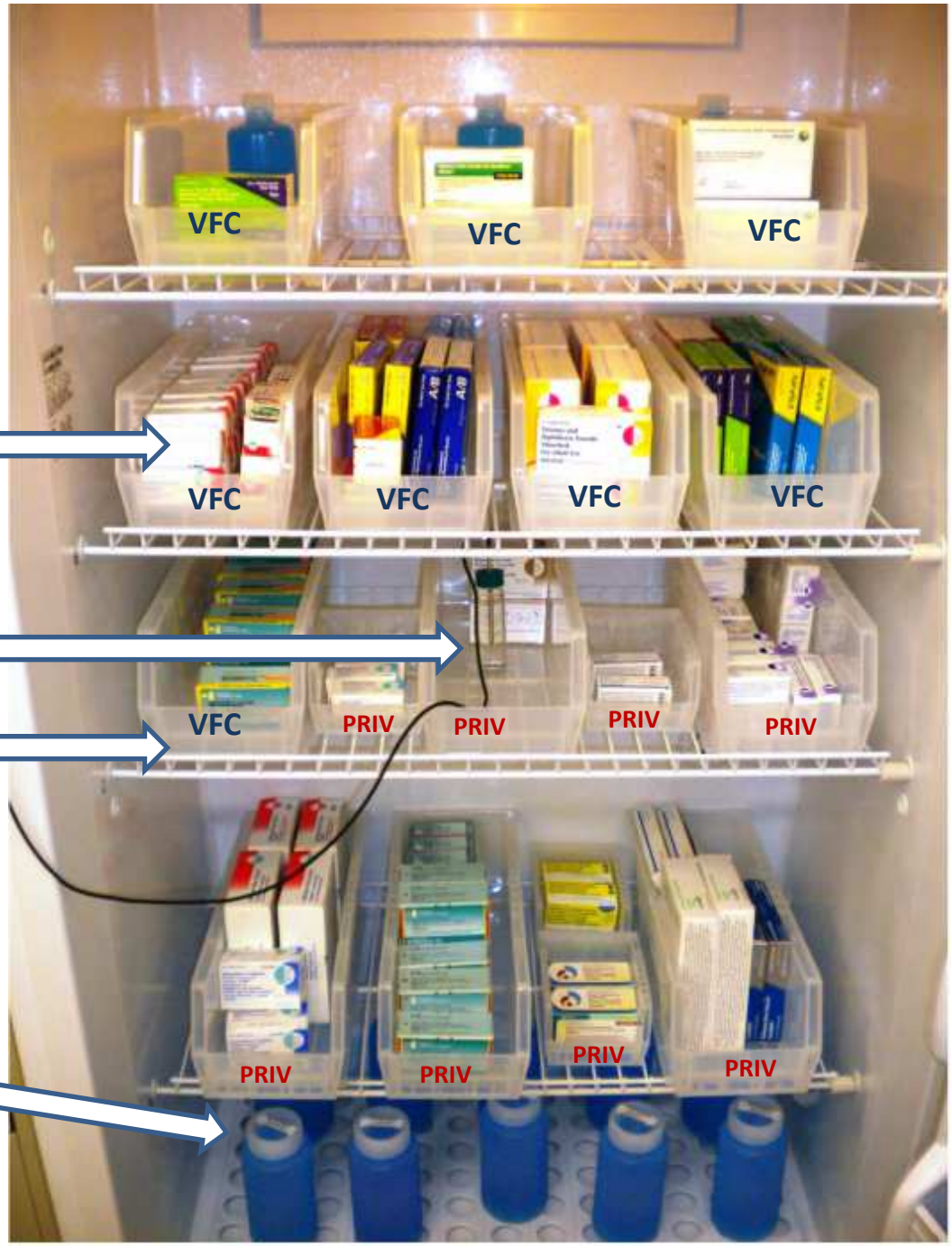
Lock keeps contents secure from unauthorized handlers

Don't use these for VFC vaccine storage!

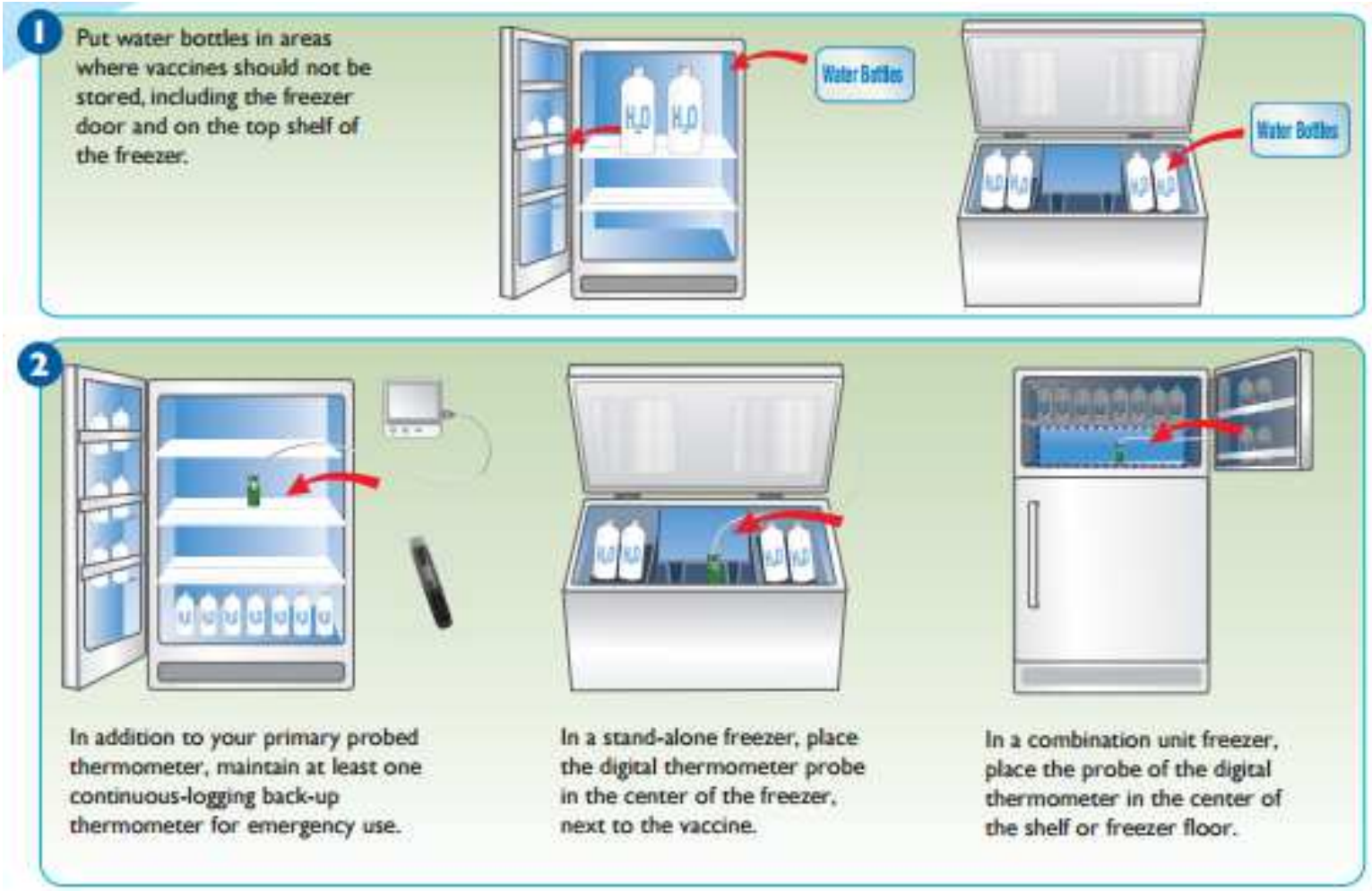
Refrigerator and freezer layout

Keeping a tidy vaccine fridge

- Minimize confusion and exposure to light, keep vaccine in their boxes until needed. Work out of one open box at a time. Please note, CDC tracks lot numbers via the box, not the vial.
- Place thermometer probe in a central location.
- Clearly label storage bins.
- Place water bottles to help reduce temperature fluctuation and block prohibited storage areas (e.g. door storage, cold air vent, bottom shelf)
- No food or drinks



The same set-up rules apply to your freezer



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Quiz time

Let's play the picture game!

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Q: How much is this fridge worth? (closest guess wins)

Q: List one thing right and one thing wrong with this picture?

Q: Is this storage unit VFC compliant?
Give three reasons for your answer


Conditioned Water Bottles


Cardboard Sheet


Bubble wrap, packing foam, or Styrofoam™


Conditioned Water Bottles


Cardboard Sheet


Temperature Monitoring Device Display (on lid)


Vaccines, Diluents, and Temperature Monitoring Device Probe


Bubble wrap, packing foam, or Styrofoam™

Q: What's the proper order for packing vaccine?

Bonus Q: What's this camel carrying?

ARKTEK passive cooler

- Holds vaccines between 0℃ and 10℃ for over a month using only a single load of ice at hot zone temperature environment of 43℃/109F.
- Can handle rough roads and harsh environments.
- Provides capacity to serve a community of up to 6,000(at 250cc per fully immunized child)
- Automatically alerts if internal temperature goes below allowable limits.

http://www.intellectualventures.com/inventions-patents/our-inventions/vaccine-cold-chain-device/

Bonus Q: Why's this baby giving you the stink eye?

A parting gift

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oregon immunization program

VACCINES FOR CHILDREN (VFC) CLINIC SELF-ASSESSMENT

1. VACCINE ELIGIBILITY SCREENING AND BILLING

- ☐ Staff must screen and document the vaccine eligibility status at every vaccination visit, for every patient.
- ☐ Staff know which patients can and cannot get VFC vaccine. http://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html).
- ☐ Vaccine administration fee charged to uninsured VFC patients is not more than $21.96 per dose.

2. DOCUMENTATION

- ☐ Review all Vaccine Management plans annually. The plans must include ALL of the following:
  - Date it was last reviewed
  - Documentation of review by Primary and Backup VFC contacts
  - Appropriate vaccine storage and handling practices
  - Vaccine shipping, receiving and transporting procedures
  - Emergency plan and procedures
  - Vaccine ordering procedures
  - Inventory Control (Stock Rotation)
  - Handling vaccine wastage

  See the Oregon Vaccine Management Guide.
- ☐ Maintain VFC documentation including temperature and borrowing logs, for three years.
- ☐ A current Vaccine Information Statement (VIS) is provided before every immunization. To sign up for email alerts when VIS are updated, go to the following http://www.immunize.org/vis/.
- ☐ Immunization documentation must be in the patient's permanent medical record and include the following:
  - Name of vaccine and the date administered

https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/vfc/Documents/VFCsitevisitChklst.pdf