Vaccine Management: Storage and Handling

Massachusetts Department of Public Health
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Director, Immunization Program

Presenter Disclosure Information

- *I, Pejman Talebian, have been asked to disclose any significant relationships with commercial entities that are either providing financial support for this program or whose products or services are mentioned during my presentations.*
  - *I have no relationships to disclose.*
- *I may discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration.*
  - *But in accordance with ACIP recommendations.*

Learning Objectives

- Summarize principles of vaccine management
- Describe current vaccine storage and handling recommendations
- Describe preventative measures to maintain refrigerator and freezer temperatures
- Discover a new tool to monitor vaccine temperatures
- List steps to protect vaccine in the event of a power outage or emergency

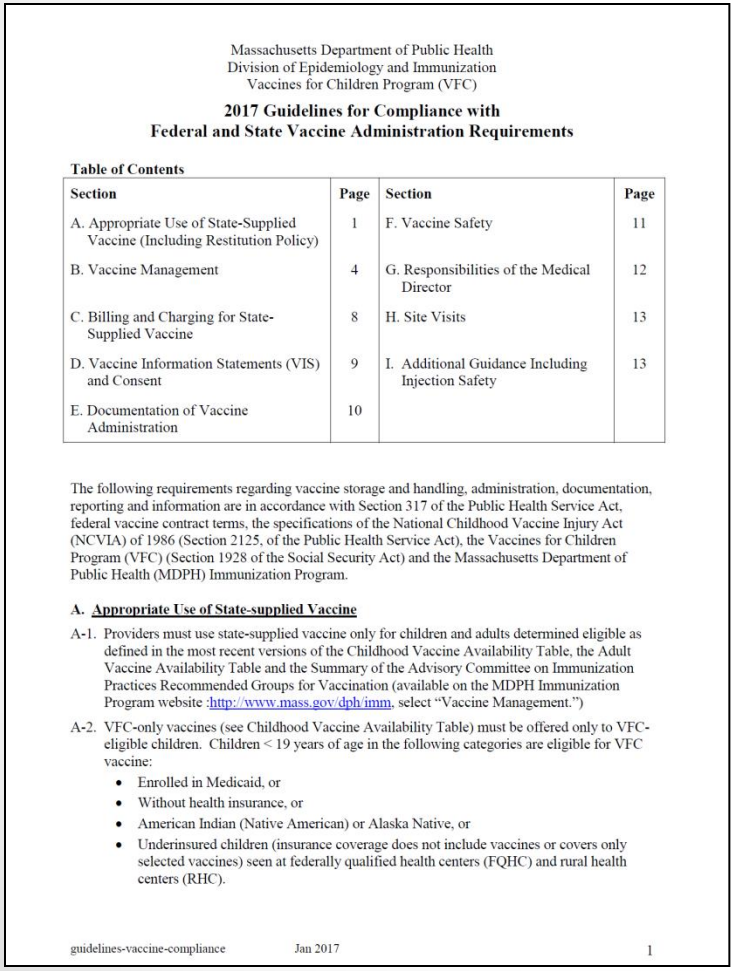
Why is Vaccine Storage & Handling important?

*"Proper vaccine storage and handling practices play a very important role in **protecting individuals and communities from vaccine-preventable diseases**.*

*Vaccine quality is the **shared responsibility of everyone**, from the time vaccine is manufactured until it is administered."* -CDC

- Proper storage and handling of vaccines protect public health and have contributed to the decrease of vaccine-preventable disease rates
- Storage and handling errors
  - Decrease potency and reduce effectiveness and protection
  - Cost thousands of dollars in wasted vaccine and revaccination
  - Loss of patient confidence

Guidelines for Compliance



Massachusetts Department of Public Health
Division of Epidemiology and Immunization
Vaccines for Children Program (VFC)

2017 Guidelines for Compliance with Federal and State Vaccine Administration Requirements

Table of Contents

The following requirements regarding vaccine storage and handling, administration, documentation, reporting and information are in accordance with Section 317 of the Public Health Service Act, federal vaccine contract terms, the specifications of the National Childhood Vaccine Injury Act (NCVIA) of 1986 (Section 2125, of the Public Health Service Act), the Vaccines for Children Program (VFC) (Section 1928 of the Social Security Act) and the Massachusetts Department of Public Health (MDPH) Immunization Program.

A. Appropriate Use of State-supplied Vaccine

A-1. Providers must use state-supplied vaccine only for children and adults determined eligible as defined in the most recent versions of the Childhood Vaccine Availability Table, the Adult Vaccine Availability Table and the Summary of the Advisory Committee on Immunization Practices Recommended Groups for Vaccination (available on the MDPH Immunization Program website :http://www.mass.gov/dph/imm, select "Vaccine Management.")

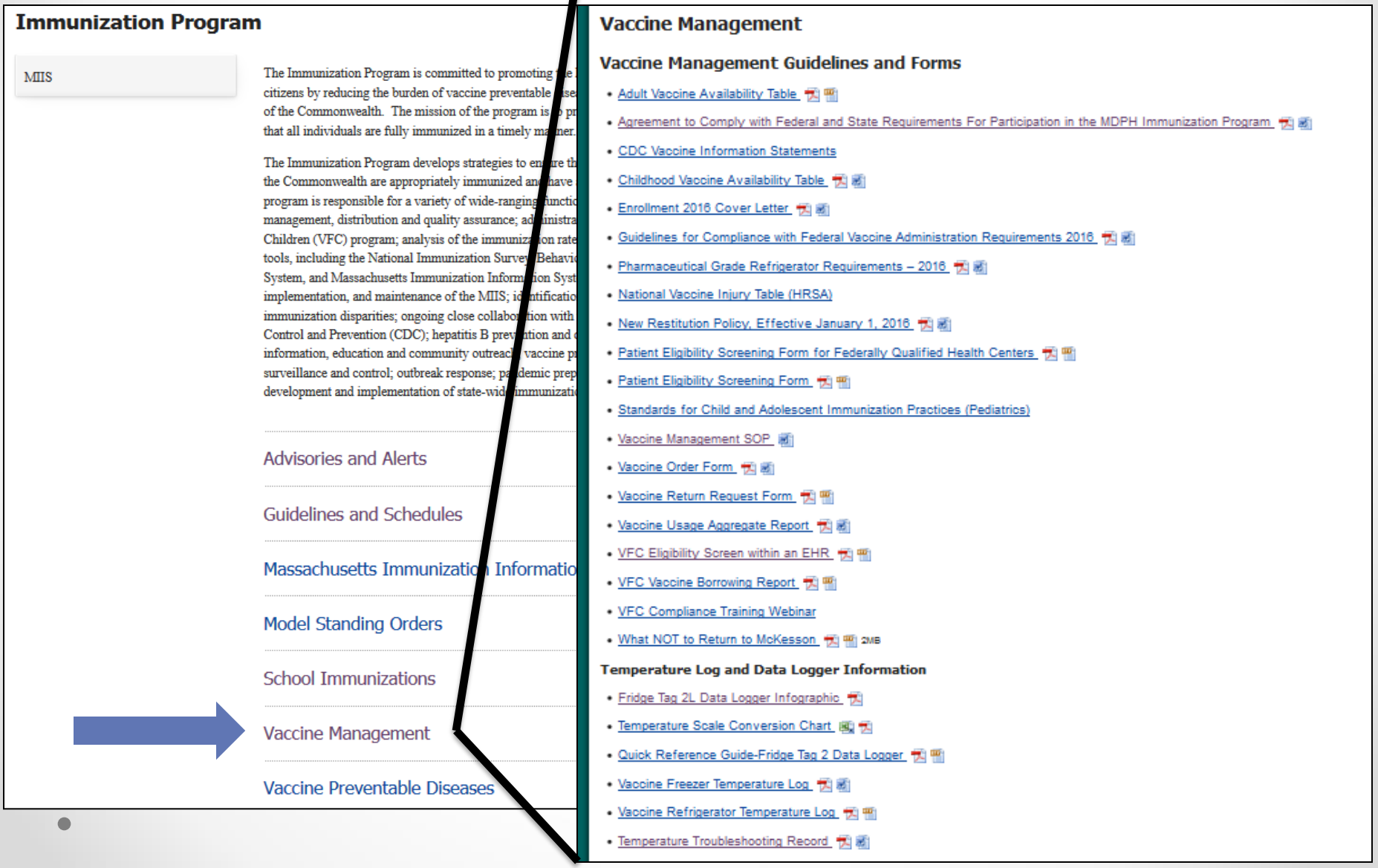
A-2. VFC-only vaccines (see Childhood Vaccine Availability Table) must be offered only to VFC-eligible children. Children < 19 years of age in the following categories are eligible for VFC vaccine:

- Enrolled in Medicaid, or
- Without health insurance, or
- American Indian (Native American) or Alaska Native, or
- Underinsured children (insurance coverage does not include vaccines or covers only selected vaccines) seen at federally qualified health centers (FQHC) and rural health centers (RHC).

guidelines-vaccine-compliance Jan 2017 1

- All vaccine storage and handling and VFC requirements and recommendations are detailed in the Guidelines for Compliance with Federal and State Vaccine Administration Requirements.
- Available on our website: www.mass.gov/dph/imm and click on 'Vaccine Management'

MDPH Immunization Program Website
www.mass.gov/dph/imm



Immunization Program

MIIS

The Immunization Program is committed to promoting the
citizens by reducing the burden of vaccine preventable dise
of the Commonwealth. The mission of the program is to pr
that all individuals are fully immunized in a timely manner.

The Immunization Program develops strategies to ensure th
the Commonwealth are appropriately immunized and have
program is responsible for a variety of wide-ranging functio
management, distribution and quality assurance; administra
Children (VFC) program; analysis of the immunization rate
tools, including the National Immunization Survey/Behavio
System, and Massachusetts Immunization Information Syst
implementation, and maintenance of the MIIS; identificatio
immunization disparities; ongoing close collaboration with
Control and Prevention (CDC); hepatitis B prevention and c
information, education and community outreach; vaccine pr
surveillance and control; outbreak response; pandemic prep
development and implementation of state-wide immunizatio

Advisories and Alerts

Guidelines and Schedules

Massachusetts Immunization Informatio

Model Standing Orders

School Immunizations

Vaccine Management

Vaccine Preventable Diseases

Vaccine Management

Vaccine Management Guidelines and Forms

- Adult Vaccine Availability Table
- Agreement to Comply with Federal and State Requirements For Participation in the MDPH Immunization Program
- CDC Vaccine Information Statements
- Childhood Vaccine Availability Table
- Enrollment 2016 Cover Letter
- Guidelines for Compliance with Federal Vaccine Administration Requirements 2016
- Pharmaceutical Grade Refrigerator Requirements – 2016
- National Vaccine Injury Table (HRSA)
- New Restitution Policy, Effective January 1, 2016
- Patient Eligibility Screening Form for Federally Qualified Health Centers
- Patient Eligibility Screening Form
- Standards for Child and Adolescent Immunization Practices (Pediatrics)
- Vaccine Management SOP
- Vaccine Order Form
- Vaccine Return Request Form
- Vaccine Usage Aggregate Report
- VFC Eligibility Screen within an EHR
- VFC Vaccine Borrowing Report
- VFC Compliance Training Webinar
- What NOT to Return to McKesson 2MB

Temperature Log and Data Logger Information

- Fridge Tag 2L Data Logger Infographic
- Temperature Scale Conversion Chart
- Quick Reference Guide-Fridge Tag 2 Data Logger
- Vaccine Freezer Temperature Log
- Vaccine Refrigerator Temperature Log
- Temperature Troubleshooting Record

CDC Storage and Handling

http://www.cdc.gov/vaccines/recs/storage/

Vaccines and Immunizations

Vaccines Home

Vaccines & Immunizations

- Vaccines and Immunizations Home
- Immunization Schedules
- Recommendations and Guidelines
  - Advisory Committee on Immunization Practices (ACIP)
  - ▶Vaccine Storage & Handling
  - Vaccine Administration
  - Reminder Systems and Strategies for Increasing Vaccination Rates
- Vaccines & Preventable Diseases
- Basics and Common Questions
- Vaccination Records
- Vaccine Safety and Adverse Events
- For Travelers
- For Specific Groups of People

Vaccines and Immunizations Home > Recommendations and Guidelines

Print page

Vaccine Storage and Handling

Recommendations and Guidelines

At a Glance

Proper vaccine storage and handling practices play a very important role in protecting individuals and communities from vaccine-preventable diseases.

Vaccine quality is the shared responsibility of everyone, from the time vaccine is manufactured until it is administered.

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What's this? Submit

CDC Medscape from WebMD

Running Time: 5:07 mins
Date Released: 06/27/2011

CDC Commentary - Make No Mistake: Vaccine Administration, Storage, and Handling

Dr. Andrew Kroger offers 7 steps to help prevent vaccine administration errors

Resources on Proper Vaccine Storage and Handling

- Keys to Storing and Handling Your Vaccine Supply is a video designed to decrease vaccine storage and handling errors and preserve the nation's vaccine supply by demonstrating to immunization providers the recommended best practices for storage and handling of vaccines. (Video is a winner of the Winter/Spring 2014 Web Health Award) May 2014
- These storage and handling fact sheets illustrate best practices for both refrigerated and frozen vaccines. Written in plain language, they include assessments to reinforce key points. While they are CDC-developed and branded fact sheets, each contains an area where you can

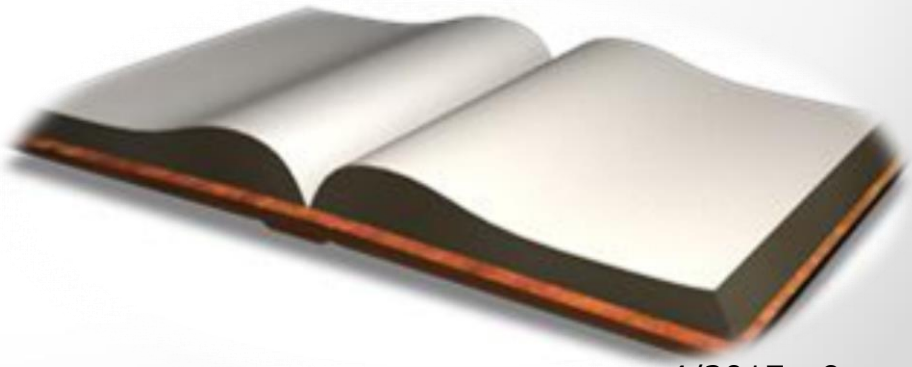
Vaccine Management

- Each provider should designate one staff member to be the Vaccine Coordinator and one back up person who is able to perform the same responsibilities.

- The Vaccine Coordinator must train other staff responsible for managing the vaccine supply.

Vaccine Management Plans

- Providers should have written vaccine management standard operating procedures (SOP) which are reviewed or updated annually or when there is any change or a new Vaccine Coordinator.
- All staff who are responsible for handling or administering vaccines must acknowledge reading the practice's SOP by signing and dating the document.

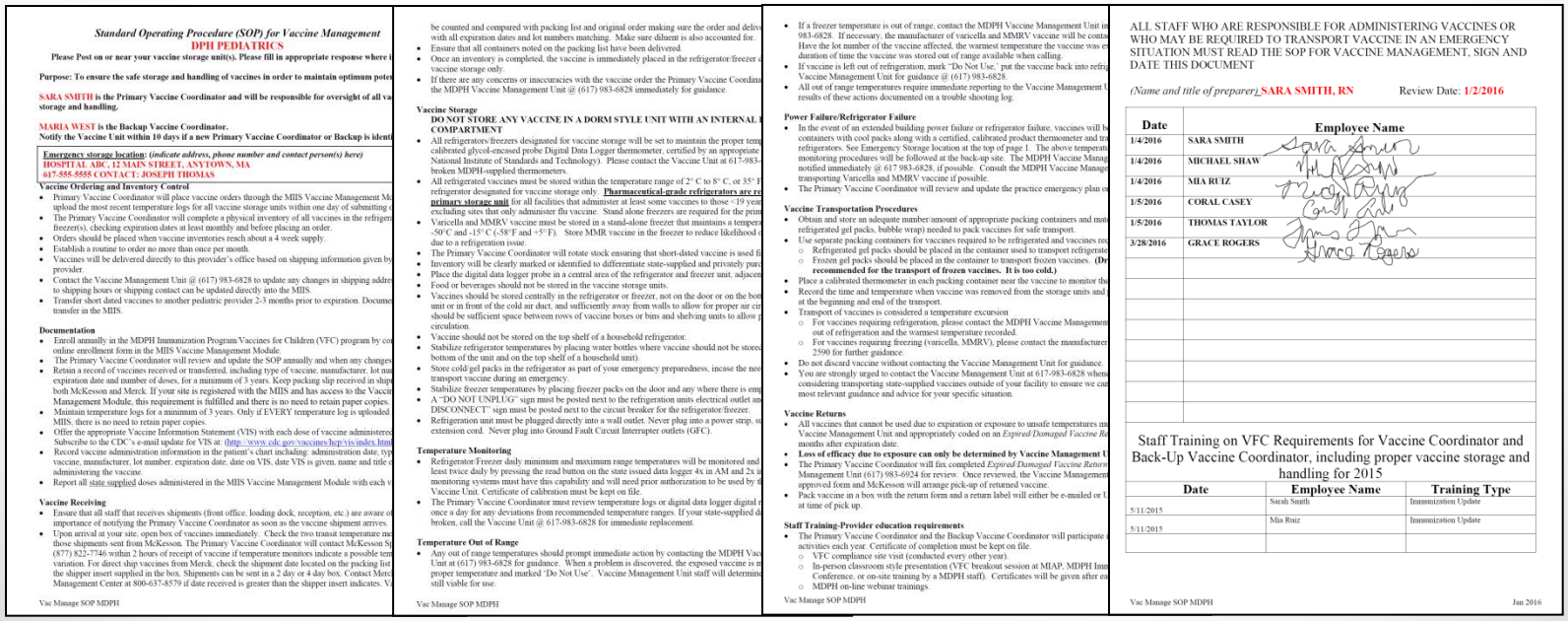


Components of Vaccine Management Standard Operating Procedure (SOP)

- Proper storage and handling of vaccines
- Vaccine receiving
- Procedure for vaccine relocation in the event of power or equipment failure
- Vaccine ordering and inventory control
- Handling damaged or expired vaccines
- Protocols for response when vaccine is stored out of temperature range
- A sample copy of MDPH's SOP for Vaccine Management can be found on our website

Updating SOP

- Update SOP annually or with any changes.
  - Have all staff who handle or administer vaccines read the updated SOP and sign and date the last page.
  - Post the SOP on the vaccine refrigerator.
  - Have any new staff member read and sign the SOP as part of their training.



Standard Operating Procedure (SOP) for Vaccine Management
DPH PEDIATRICS
Please Post on or near your vaccine storage unit(s). Please fill in appropriate response where i

Purpose: To ensure the safe storage and handling of vaccines in order to maintain optimum pote

SARA SMITH is the Primary Vaccine Coordinator and will be responsible for oversight of all va storage and handling.

MARIA WEST is the Backup Vaccine Coordinator.
Notify the Vaccine Unit within 10 days if a new Primary Vaccine Coordinator or Backup is identi

Emergency storage location: *(indicate address, phone number and contact person(s) here)*
HOSPITAL ABC , 12 MAIN STREET, ANYTOWN, MA
617-555-5555 CONTACT: JOSEPH THOMAS

Vaccine Ordering and Inventory Control
- Primary Vaccine Coordinator will place vaccine orders through the MIIS Vaccine Management Mo upload the most recent temperature logs for all vaccine storage units within one day of submitting
- The Primary Vaccine Coordinator will complete a physical inventory of all vaccines in the refrige freezer(s), checking expiration dates at least monthly and before placing an order.
- Orders should be placed when vaccine inventories reach about a 4 week supply.
- Establish a routine to order no more than once per month.
- Vaccines will be delivered directly to this provider's office based on shipping information given by provider.
- Contact the Vaccine Management Unit @ (617) 983-6828 to update any changes in shipping addre to shipping hours or shipping contact can be updated directly into the MIIS.
- Transfer short dated vaccines to another pediatric provider 2-3 months prior to expiration. Docume transfer in the MIIS.

Documentation
- Enroll annually in the MDPH Immunization Program Vaccines for Children (VFC) program by co online enrollment form in the MIIS Vaccine Management Module.
- The Primary Vaccine Coordinator will review and update the SOP annually and when any changes
- Retain a record of vaccines received or transferred, including type of vaccine, manufacturer, lot nu expiration date and number of doses, for a minimum of 3 years. Keep packing slip received in ship both McKesson and Merck. If your site is registered with the MIIS and has access to the Vaccir Management Module, this requirement is fulfilled and there is no need to retain paper copies.
- Maintain temperature logs for a minimum of 3 years. Only if EVERY temperature log is uploaded MIIS, there is no need to retain paper copies.
- Offer the appropriate Vaccine Information Statement (VIS) with each dose of vaccine administered Subscribe to the CDC's e-mail update for VIS at (http://www.cdc.gov/vaccines/hcp/vis/index.html
- Record vaccine administration information in the patient's chart including: administration date, typ vaccine, manufacturer, lot number, expiration date, date on VIS, date VIS is given, name and title administering the vaccine.
- Report all state supplied doses administered in the MIIS Vaccine Management Module with each v

Vaccine Receiving
- Ensure that all staff that receives shipments (front office, loading dock, reception, etc.) are aware o importance of notifying the Primary Vaccine Coordinator as soon as the vaccine shipment arrives.
- Upon arrival at your site, open box of vaccines immediately. Check the two transit temperature m those shipments sent from McKesson. The Primary Vaccine Coordinator will contact McKesson Sp (877) 822-7746 within 2 hours of receipt of vaccine if temperature monitors indicate a possible tem variation. For direct ship vaccines from Merck, check the shipment date located on the packing list the shipper insert supplied in the box. Shipments can be sent in a 2 day or 4 day box. Contact Merc Management Center at 800-637-8579 if date received is greater than the shipper insert indicates. V

Vac Manage SOP MDPH

be counted and compared with packing list and original order making sure the order and deliv with all expiration dates and lot numbers matching. Make sure diluent is also accounted for.
- Ensure that all containers noted on the packing list have been delivered.
- Once an inventory is completed, the vaccine is immediately placed in the refrigerator/freezer vaccine storage only.
- If there are any concerns or inaccuracies with the vaccine order the Primary Vaccine Coordina the MDPH Vaccine Management Unit @ (617) 983-6828 immediately for guidance.

Vaccine Storage
DO NOT STORE ANY VACCINE IN A DORM STYLE UNIT WITH AN INTERNAL COMPARTMENT
- All refrigerators/freezers designated for vaccine storage will be set to maintain the proper temp calibrated glycol-encased probe Digital Data Logger thermometer, certified by an appropriate National Institute of Standards and Technology). Please contact the Vaccine Unit at 617-983- broken MDPH-supplied thermometers.
- All refrigerated vaccines must be stored within the temperature range of 2° C to 8° C, or 35° F refrigerator designated for vaccine storage only. **Pharmaceutical-grade refrigerators are re primary storage unit** for all facilities that administer at least some vaccines to those <19 yea excluding sites that only administer flu vaccine. Stand alone freezers are required for the prim
- Varicella and MMRV vaccine must be stored in a stand-alone freezer that maintains a temper -50°C and -15° C (-58°F and +5° F). Store MMR vaccine in the freezer to reduce likelihood due to a refrigeration issue.
- The Primary Vaccine Coordinator will rotate stock ensuring that short-dated vaccine is used fi
- Inventory will be clearly marked or identified to differentiate state-supplied and privately pur
- Place the digital data logger probe in a central area of the refrigerator and freezer unit, adjacen
- Food or beverages should not be stored in the vaccine storage units.
- Vaccines should be stored centrally in the refrigerator or freezer, not on the door or on the bot unit or in front of the cold air duct, and sufficiently away from walls to allow for proper air cir should be sufficient space between rows of vaccine boxes or bins and shelving units to allow circulation.
- Vaccine should not be stored on the top shelf of a household refrigerator.
- Stabilize refrigerator temperatures by placing water bottles where vaccine should not be store bottom of the unit and on the top shelf of a household unit).
- Store cold/gel packs in the refrigerator as part of your emergency preparedness, incase the ne transport vaccine during an emergency.
- Stabilize freezer temperatures by placing freezer packs on the door and any where there is em
- A "DO NOT UNPLUG" sign must be posted next to the refrigeration units electrical outlet an DISCONNECT" sign must be posted next to the circuit breaker for the refrigerator/freezer.
- Refrigeration unit must be plugged directly into a wall outlet. Never plug into a power strip, s extension cord. Never plug into Ground Fault Circuit Interrupter outlets (GFC).

Temperature Monitoring
- Refrigerator/Freezer daily minimum and maximum range temperatures will be monitored and least twice daily by pressing the read button on the state issued data logger 4x in AM and 2x i monitoring systems must have this capability and will need prior authorization to be used by t Vaccine Unit. Certificate of calibration must be kept on file.
- The Primary Vaccine Coordinator must review temperature logs or digital data logger digital once a day for any deviations from recommended temperature ranges. If your state-supplied broken, call the Vaccine Unit @ 617-983-6828 for immediate replacement.

Temperature Out of Range
- Any out of range temperatures should prompt immediate action by contacting the MDPH Vac Unit at (617) 983-6828 for guidance. When a problem is discovered, the exposed vaccine is proper temperature and marked 'Do Not Use'. Vaccine Management Unit staff will determin still viable for use.

Vac Manage SOP MDPH

- If a freezer temperature is out of range, contact the MDPH Vaccine Management Unit i 983-6828. If necessary, the manufacturer of varicella and MMRV vaccine will be conta Have the lot number of the vaccine affected, the warmest temperature the vaccine was e duration of time the vaccine was stored out of range available when calling.
- If vaccine is left out of refrigeration, mark "Do Not Use," put the vaccine back into refrig Vaccine Management Unit for guidance @ (617) 983-6828.
- All out of range temperatures require immediate reporting to the Vaccine Management U results of these actions documented on a trouble shooting log.

Power Failure/Refrigerator Failure
- In the event of an extended building power failure or refrigerator failure, vaccines will be containers with cool packs along with a certified, calibrated product thermometer and tr refrigerators. See Emergency Storage location at the top of page 1. The above temperat monitoring procedures will be followed at the back-up site. The MDPH Vaccine Manag notified immediately @ 617 983-6828, if possible. Consult the MDPH Vaccine Manage transporting Varicella and MMRV vaccine if possible.
- The Primary Vaccine Coordinator will review and update the practice emergency plan o

Vaccine Transportation Procedures
- Obtain and store an adequate number/amount of appropriate packing containers and mat refrigerated gel packs, bubble wrap) needed to pack vaccines for safe transport.
- Use separate packing containers for vaccines required to be refrigerated and vaccines re
  - Refrigerated gel packs should be placed in the container used to transport refrigerate
  - Frozen gel packs should be placed in the container to transport frozen vaccines. **(Dr recommended for the transport of frozen vaccines. It is too cold.)**
- Place a calibrated thermometer in each packing container near the vaccine to monitor the
- Record the time and temperature when vaccine was removed from the storage units and at the beginning and end of the transport.
- Transport of vaccines is considered a temperature excursion
  - For vaccines requiring refrigeration, please contact the MDPH Vaccine Management out of refrigeration and the warmest temperature recorded.
  - For vaccines requiring freezing (varicella, MMRV), please contact the manufacturer 2590 for further guidance.
- Do not discard vaccine without contacting the Vaccine Management Unit for guidance.
- You are strongly urged to contact the Vaccine Management Unit at 617-983-6828 whene considering transporting state-supplied vaccines outside of your facility to ensure we ca most relevant guidance and advice for your specific situation.

Vaccine Returns
- All vaccines that cannot be used due to expiration or exposure to unsafe temperatures m Vaccine Management Unit and appropriately coded on an *Expired/Damaged Vaccine Re* months after expiration date.
- **Loss of efficacy due to exposure can only be determined by Vaccine Management U**
- The Primary Vaccine Coordinator will fax completed *Expired/Damaged Vaccine Return* Management Unit (617) 983-6924 for review. Once reviewed, the Vaccine Management approved form and McKesson will arrange pick-up of returned vaccine.
- Pack vaccine in a box with the return form and a return label will either be e-mailed or at time of pick up.

Staff Training-Provider education requirements
- The Primary Vaccine Coordinator and the Backup Vaccine Coordinator will participate activities each year. Certificate of completion must be kept on file.
  - VFC compliance site visit (conducted every other year).
  - In-person classroom style presentation (VFC' breakout session at MIAP, MDPH Imm Conference, or on-site training by a MDPH staff). Certificates will be given after e
  - MDPH on-line webinar trainings.

Vac Manage SOP MDPH

ALL STAFF WHO ARE RESPONSIBLE FOR ADMINISTERING VACCINES OR WHO MAY BE REQUIRED TO TRANSPORT VACCINE IN AN EMERGENCY SITUATION MUST READ THE SOP FOR VACCINE MANAGEMENT, SIGN AND DATE THIS DOCUMENT

(Name and title of preparer) **SARA SMITH, RN** Review Date: **1/2/2016**

Date	Employee Name
1/4/2016	SARA SMITH
1/4/2016	MICHAEL SHAW
1/4/2016	MIA RUIZ
1/5/2016	CORAL CASEY
1/5/2016	THOMAS TAYLOR
3/28/2016	GRACE ROGERS

Staff Training on VFC Requirements for Vaccine Coordinator and Back-Up Vaccine Coordinator, including proper vaccine storage and handling for 2015

Date	Employee Name	Training Type
5/11/2015	Sarah Smith	Immunization Update
5/11/2015	Mia Ruiz	Immunization Update

Vac Manage SOP MDPH Jan 2016

Vaccine Coordinator Responsibilities

- Order vaccine and oversee inventory
- Receive vaccine and refrigerate/freeze immediately
- Provide proper storage and handling
- Handle damaged, wasted and expired vaccine
- Respond when vaccine is out of required temperature range
  - If have state-supplied vaccines contact MDPH Vaccine Unit to determine if vaccine has been damaged (617-983-6828)
  - If only have private purchase vaccines contract the vaccine manufacturer directly

Vaccine Inventory Management

- Limit access to authorized personnel
- Order vaccines regularly, do not stockpile
- Organize vaccine with shortest shelf life in front
- Conduct and log vaccine inventory monthly
- Rotate vaccines and monitor expiration dates

Receiving Vaccine

- Examine shipment immediately upon arrival
- If problems (for state-supplied vaccines), report to MDPH within two hours
- Check contents against packing slip
- Check vaccine expiration dates
- Examine contents for damage
- Check temperature monitor
- Immediately place in appropriate storage
- Keep a shipping box on hand to use when returning any damaged or expired vaccine

Vaccine Storage

- Maintain refrigerator temperature between 2°C and 8°C (36°F and 46°F).
- Maintain freezer temperature between -50°C and -15°C (-58°F and +5°F) for Varivax, ProQuad, and Zostavax vaccines.
- Place temperature data logger in a central area of the storage unit, adjacent to the vaccines and away from any air vents.

Common Adult Vaccines

Refrigerator

- Hepatitis A
- Hepatitis B
- Human Papillomavirus (HPV)
- Measles, Mumps, Rubella (MMR)
- Meningococcal Conjugate (MCV4)
- Meningococcal Group B
- Pneumococcal Conjugate
- Pneumococcal Polysaccharide
- Tetanus and Diphtheria (Td)
- Tetanus, Diphtheria, Acellular Pertussis (Tdap)

Freezer

- Varicella
- Zoster
- Measles, Mumps, Rubella (MMR)

Vaccine Storage Units

- CDC and MDPH strongly recommend stand alone refrigerators and stand alone freezers.
- MDPH now requires a pharmacy grade refrigerator for all sites that administer vaccines to children and highly recommends for all practices.
- A stand alone freezer that can maintain the proper temperatures is acceptable.

Pharmaceutical Grade Refrigerator

- Although there is no clear description of a pharmaceutical refrigerator, we have identified the following characteristics:
  - Internal fans to disperse cold air throughout the unit, eliminating cold pockets of air
  - Wire racks to allow better air flow
  - No storage bins, or shelves on door
  - Typically, pharmaceutical grade refrigerators have a narrow operating range (less than 2 degrees C or 3 degrees F)

Loading Vaccines

- Keep vaccines in original manufacturer packaging
  - Don't remove individual vials from cardboard boxes
- Place vaccine boxes in trays
- Organize vaccines by type, state/private, to facilitate quick retrieval and minimize time with refrigerator door open
- Avoid over-filling refrigerator and hindering air circulation
  - Do not store vaccines on the bottom shelf or near vents

Stabilize Your Refrigerator

Stabilize your refrigerator temperatures by placing water bottles where vaccine should not be stored (on bottom shelf)

Store cold packs in the refrigerator as part of emergency preparedness, in case you need to transport vaccine during an emergency.

Unacceptable Vaccine Storage

Unacceptable Vaccine Storage

Monitor Temperatures

- Record temperatures twice daily
  - First thing in the morning
  - End of the work day
  - Temperature logs must be retained for at least 3 years
  - Monitor for out-of-range temperatures
- Place temperature logs on front of unit

Appropriate Temperature Monitoring & Documentation

- NIST certified calibrated digital data loggers for continuous 24-hour temperature monitoring for **all** vaccine storage units at all pediatric providers (any site that administers vaccines to those <19 years of age) is now required by MDPH and is strongly recommended for all adult providers.
- These data loggers should have a biosafe glycol-encased detachable temperature probe.
- The data logger must record the minimum and maximum temperature each day.
- Providers must still physically acknowledge the high/low temperatures at least twice daily.

Appropriate Temperature Monitoring & Documentation

- Immediate action must be taken if temperatures are out of range.
- For state-supplied vaccines, report all vaccine storage issues, including temperature excursions, to:
  - Vaccine Management Unit at 617-983-6828.
- For privately purchased vaccines, contact each manufacturer to determine if you can continue to administer their vaccine.

Data Loggers

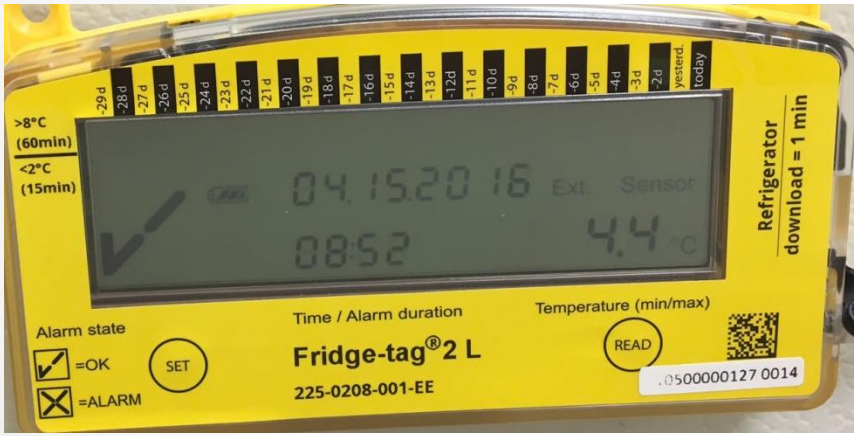
- Come in all shapes and sizes
- Must be NIST certified
- Able to measure product temperature with a detachable probe

MDPH Has Provided Fridge-tag2L® Logger to All Pediatric Providers

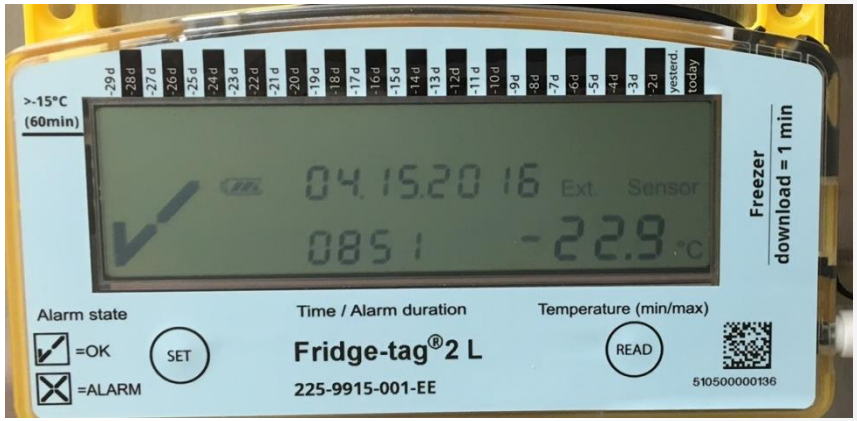
- NIST certified
- No software required; easy to install and use
  - Simple YouTube instructional videos
- All pediatric practices have received them for all their vaccine storage units
  - All practices can purchase units at state pricing

Fridge-tag 2L® Loggers

Refrigerator



Freezer



Calibration reports

Refrigerator

THERMCO PRODUCTS, INC

Accreditation No.: 69071 to ISO/IEC 17025:2005

PRECISION DIGITAL THERMOMETER CALIBRATION REPORT

Customer MA Dept of Public Health 305 South Street, Jamaica Plain, MA 02130

INSTRUMENT INFORMATION

Standard Temperature	Temp Reading	Correction +/-	In Tolerance
4.0	4	0	Pass

Calibration Date: 01/15/2016 Calibration Due Date: 01/15/2019

Serial No.: 510500000127 0014 Report No.: MA5091

Model No.: FridgeTag 2L

Range: -30/50 Divisions: 0.1° Scale: °C

* If the sign given is + the true temperature is higher than the indicated temperature, If the sign given is - the true temperature is lower than the indicated temperature.

Expanded Uncertainty: ± 0.050

Test Reference Documents
ASTM E644-09 Standard Test Method 6.2.1 Volume 14.03.2011
NIST Technical Note 1265, Guidelines for Realizing the International Temperature Scale of 1990 (ITS-90).

NIST Traceable Equipment Used to Perform Testing:

Manufacture	Description	Model Number	Serial Numbers	Calibration Date	Calibration Due Date
Fluke /Hart Scientific	Black Stack PRT Scanner Module	2562	A56655	12/10/2015	12/10/2016
Burns	100ohm PRT Probe's	5626-15	3543	12/10/2015	12/10/2016
"	"	"	1096	12/10/2015	12/10/2016
"	"	"	1095	12/10/2015	12/10/2016
"	"	"	856968	12/10/2015	12/10/2016
"	"	"	853277	12/10/2015	12/10/2016

Laboratory Environmental Conditions:

Temperature	Humidity	Onsite Calibration
23°C +/- 5°C	40% - 60%	Yes

Thermometer Integrity:
Complete visual inspection for any physical damage.

Calibration Procedure Used:
The NIST traceable calibration instruments listed were used to calibrate the described thermometer listed above against the NIST traceable reference standards in accordance with ISO/IEC 17025 calibration procedures at the noted test temperatures by a comparison method. The standards used have been certified by an ISO/IEC 17025/ A2LA accredited calibration laboratory

The calibration results published in this certificate were obtained using equipment capable of producing results that are traceable to NIST and through NIST to the International System of Units (SI). The uncertainty of measurement associated with the measurement result reported in this certificate is available from Thermco Products Inc. upon request and was accounted for in making the decision of compliance or noncompliance with the relevant specification identified above.

The reported expanded uncertainty of measurement is stated as the combined standard uncertainty of measurement multiplied by the coverage factor k,(k =2) such that the coverage probability corresponds to approximately 95 %.

CALIBRATION TECHNICIAN: John Williams CALIBRATION APPROVED BY: Rick Casario

This certificate may not be reproduced without the express written approval of THERMCO PRODUCTS, INC.

www.ThermcoProducts.com
10 Millpond Drive Unit #10 Lafayette, NJ 07848 - Phone: 973.300.9100

Freezer

THERMCO PRODUCTS, INC

Accreditation No.: 69071 to ISO/IEC 17025:2005

PRECISION DIGITAL THERMOMETER CALIBRATION REPORT

Customer MA Dept of Public Health 305 South Street, Jamaica Plain, MA 02130

INSTRUMENT INFORMATION

Standard Temperature	Temp Reading	Correction +/-	In Tolerance
-20.0	-20	0	Pass

Calibration Date: 01/15/2016 Calibration Due Date: 01/15/2019

Serial No.: 510500000136 Report No.: MA5355

Model No.: FreezeTag 2L

Range: -30/55 Divisions: 0.1° Scale: °C

* If the sign given is + the true temperature is higher than the indicated temperature, If the sign given is - the true temperature is lower than the indicated temperature.

Expanded Uncertainty: ± 0.050

Test Reference Documents
ASTM E644-09 Standard Test Method 6.2.1 Volume 14.03.2011
NIST Technical Note 1265, Guidelines for Realizing the International Temperature Scale of 1990 (ITS-90).

NIST Traceable Equipment Used to Perform Testing:

Manufacture	Description	Model Number	Serial Numbers	Calibration Date	Calibration Due Date
Fluke /Hart Scientific	Black Stack PRT Scanner Module	2562	A56655	12/10/2015	12/10/2016
Burns	100ohm PRT Probe's	5626-15	3543	12/10/2015	12/10/2016
"	"	"	1096	12/10/2015	12/10/2016
"	"	"	1095	12/10/2015	12/10/2016
"	"	"	856968	12/10/2015	12/10/2016
"	"	"	853277	12/10/2015	12/10/2016

Laboratory Environmental Conditions:

Temperature	Humidity	Onsite Calibration
23°C +/- 5°C	40% - 60%	Yes

Thermometer Integrity:
Complete visual inspection for any physical damage.

Calibration Procedure Used:
The NIST traceable calibration instruments listed were used to calibrate the described thermometer listed above against the NIST traceable reference standards in accordance with ISO/IEC 17025 calibration procedures at the noted test temperatures by a comparison method. The standards used have been certified by an ISO/IEC 17025/ A2LA accredited calibration laboratory.

The calibration results published in this certificate were obtained using equipment capable of producing results that are traceable to NIST and through NIST to the international System of Units (SI). The uncertainty of measurement associated with the measurement result reported in this certificate is available from Thermco Products Inc. upon request and was accounted for in making the decision of compliance or noncompliance with the relevant specification identified above.

The reported expanded uncertainty of measurement is stated as the combined standard uncertainty of measurement multiplied by the coverage factor k (k =2) such that the coverage probability corresponds to approximately 95 %.

CALIBRATION TECHNICIAN: John Williams CALIBRATION APPROVED BY: Rick Casario

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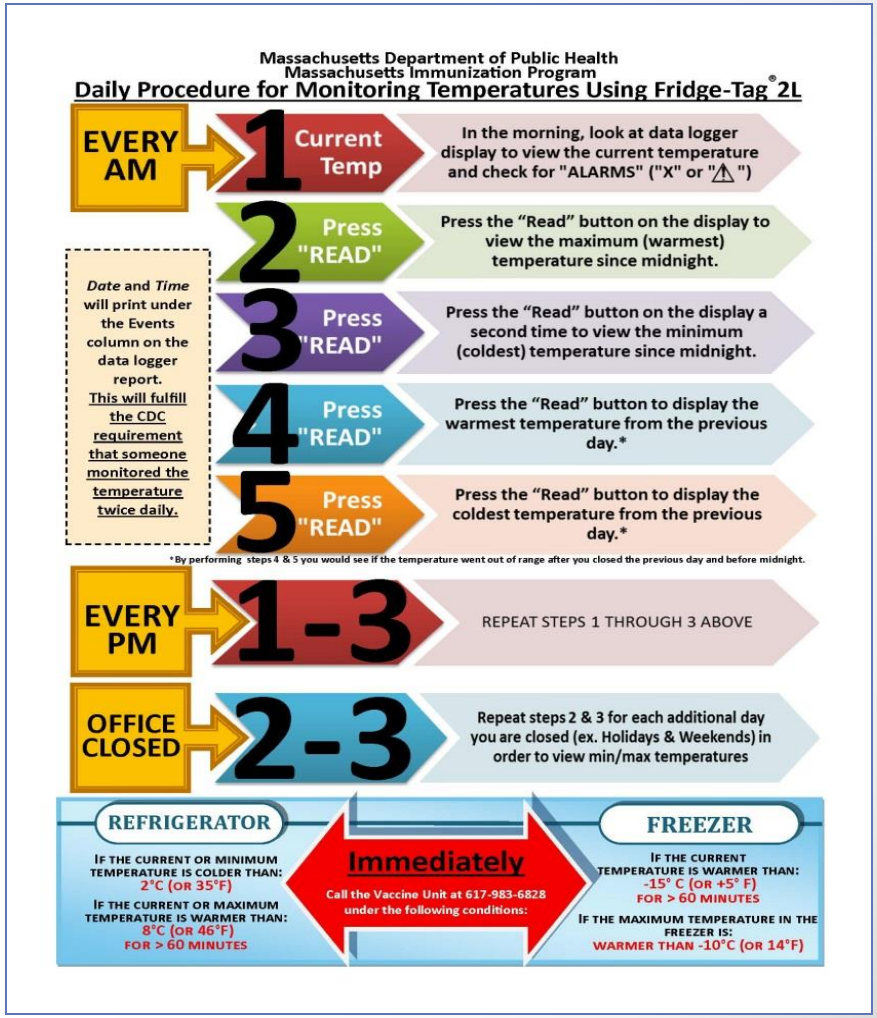
www.ThermcoProducts.com
10 Millpond Drive Unit #10 Lafayette, NJ 07848 - Phone: 973.300.9100

Closer Measurement of Vaccine Temperature

- Fridge-tag2L® Logger measures the temperature of a 5 ml glycol solution
- Most vaccines are 1 ml or less
- Minimum and maximum temperatures being measured more closely reflect the temperature of the vaccine and with more sensitivity to temperature fluctuations
- Traditional bottle thermometer measures the temperature of a 30 ml glycol solution

Documenting Temperature

- With the Fridge-tag2L® you can document temperatures 2x/day, with the time and min/max temp by pressing the 'Read' button 2x/day
- Infographic on MDPH website www.mass.gov/dph/imm under 'Vaccine Management'



Reviewing temp logs

Events - recor
the 'Read' but
pressed. Doc
the temperatu
reviewed. There sh uld
be two times for eac day
the office is open.

Avg. Tem
average t
each day.
be aroun
that day an alarm wa

Lower Alarm Limit – s
status (ok or ALARM)
minimum temp., time
limit (2°C), and the ea

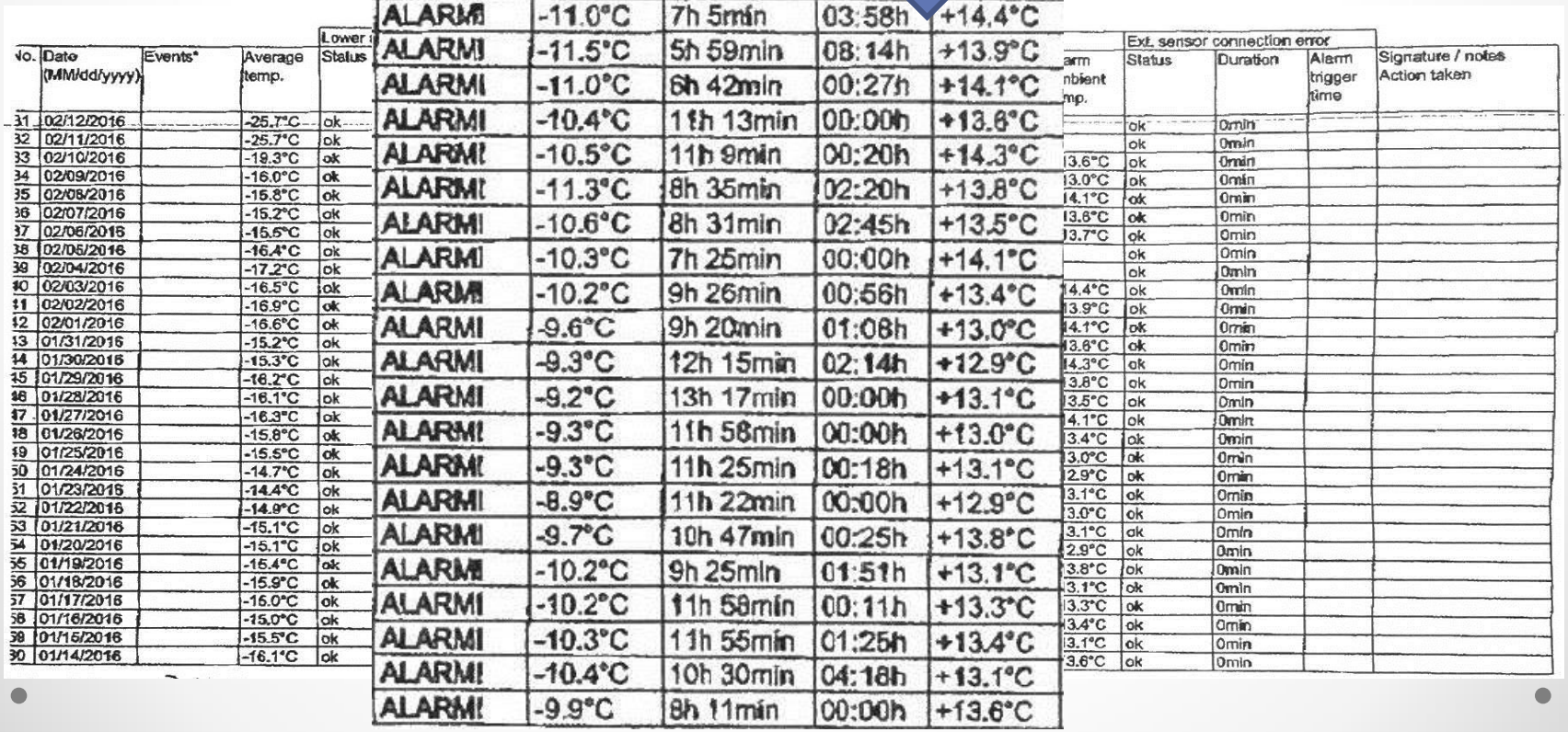
Upper Alarm Limit – shows
status (ok or ALARM), the
maximum temp., time above the
limit (8°C), and the earliest time
that day an alarm was triggered.

No.	Date (MM/dd/yyyy)	Events[2]	Average temp.	Lower alarm limit: Status	Lower alarm limit: Min. temp.	Lower alarm limit: Cumulative daily time below the limit	Lower alarm limit: Alarm trigger time	Upper alarm limit: Status	Upper alarm limit: Max. temp.	Upper alarm limit: Cumulative daily time above the limit	Upper alarm limit: Alarm trigger time
29	03/14/2016	05:48,15:48	+4.5°C	ok	+4.3°C	0min		ok	+4.9°C	0min	
30	03/13/2016		+4.5°C	ok	+4.3°C	0min		ok	+4.9°C	0min	
31	03/12/2016		+4.5°C	ok	+4.3°C	0min		ok	+4.9°C	0min	
32	03/11/2016	06:32,16:18	+4.5°C	ok	+4.3°C	0min		ok	+4.9°C	0min	
33	03/10/2016	06:45,16:43	+4.5°C	ok	+4.3°C	0min		ok	+5.0°C	0min	
34	03/09/2016	06:45,16:39	+4.5°C	ok	+4.3°C	0min		ok	+5.0°C	0min	
35	03/08/2016	06:38,16:39	+4.6°C	ok	+4.3°C	0min		ok	+5.2°C	0min	
36	03/07/2016	06:40,16:42	+4.6°C	ok	+4.4°C	0min		ok	+5.1°C	0min	
22	03/21/2016	06:42	+4.4°C	ok	+4.1°C	0min		ok	+5.1°C	0min	
23	03/20/2016		+4.4°C	ok	+4.1°C	0min		ok	+5.0°C	0min	
24	03/19/2016		+4.4°C	ok	+4.1°C	0min		ok	+5.1°C	0min	
25	03/18/2016	05:53,15:13	+4.4°C	ok	+4.1°C	0min		ok	+5.1°C	0min	
26	03/17/2016	05:49,15:43	+4.4°C	ok	+4.0°C	0min		ok	+5.1°C	0min	
27	03/16/2016	05:41,15:33	+4.5°C	ok	+4.1°C	0min		ok	+5.2°C	0min	
28	03/15/2016	05:48,15:39	+4.5°C	ok	+4.3°C	0min		ok	+5.0°C	0min	

1) Sampling and data analysis every minute
2) t = time / date changed, hh:mm = status checked

Freez nple #1

the frequency uration out of



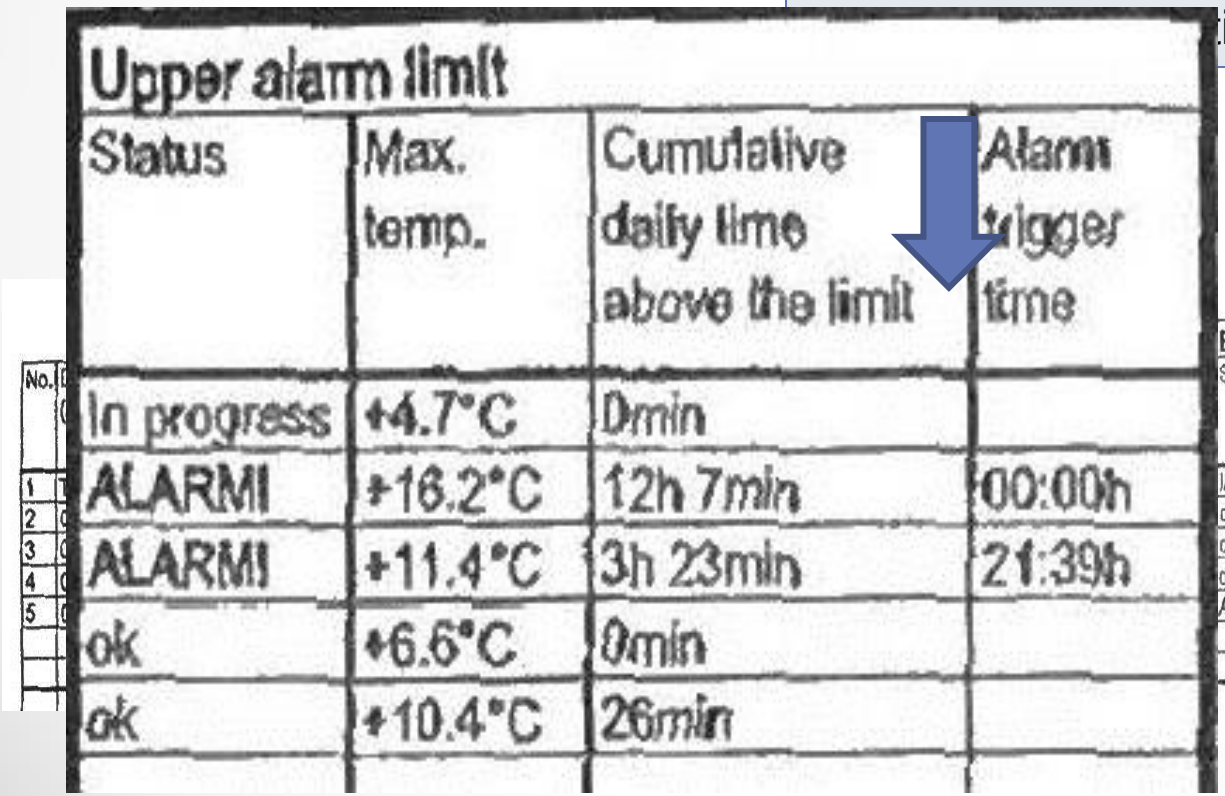
Upper alarm limit				
Status	Max. temp.	Duration out of range	Alarm trigger time	Alarm ambient temp.
ok	-25.4°C	0min		
ok	-25.4°C	0min		
ALARM!	-10.7°C	6h 7min	01:14h	+13.6°C
ALARM!	-10.5°C	8h 39min	01:38h	+13.0°C
ALARM!	-11.0°C	9h 34min	01:48h	+14.1°C
ALARM!	-10.7°C	11h 19min	00:15h	+13.6°C
ALARM!	-10.6°C	10h 13min	00:54h	13.7°C
ok	-12.1°C	7h 18min		
ok	-12.6°C	4h 48min		
ALARM!	-11.0°C	7h 5min	03:58h	+14.4°C
ALARM!	-11.5°C	5h 59min	08:14h	+13.9°C
ALARM!	-11.0°C	6h 42min	00:27h	+14.1°C
ALARM!	-10.4°C	11h 13min	00:00h	+13.6°C
ALARM!	-10.5°C	11h 9min	00:20h	+14.3°C
ALARM!	-11.3°C	8h 35min	02:20h	+13.8°C
ALARM!	-10.6°C	8h 31min	02:45h	+13.5°C
ALARM!	-10.3°C	7h 25min	00:00h	+14.1°C
ALARM!	-10.2°C	9h 26min	00:56h	+13.4°C
ALARM!	-9.6°C	9h 20min	01:08h	+13.0°C
ALARM!	-9.3°C	12h 15min	02:14h	+12.9°C
ALARM!	-9.2°C	13h 17min	00:00h	+13.1°C
ALARM!	-9.3°C	11h 58min	00:00h	+13.0°C
ALARM!	-9.3°C	11h 25min	00:18h	+13.1°C
ALARM!	-8.9°C	11h 22min	00:00h	+12.9°C
ALARM!	-9.7°C	10h 47min	00:25h	+13.8°C
ALARM!	-10.2°C	9h 25min	01:51h	+13.1°C
ALARM!	-10.2°C	11h 58min	00:11h	+13.3°C
ALARM!	-10.3°C	11h 55min	01:25h	+13.4°C
ALARM!	-10.4°C	10h 30min	04:18h	+13.1°C
ALARM!	-9.9°C	8h 11min	00:00h	+13.6°C

No.	Date (MM/dd/yyyy)	Events*	Average temp.	Lower alarm limit Status
31	02/12/2016		-25.7°C	ok
32	02/11/2016		-25.7°C	ok
33	02/10/2016		-19.3°C	ok
34	02/09/2016		-16.0°C	ok
35	02/08/2016		-15.8°C	ok
36	02/07/2016		-15.2°C	ok
37	02/06/2016		-15.5°C	ok
38	02/05/2016		-16.4°C	ok
39	02/04/2016		-17.2°C	ok
40	02/03/2016		-16.5°C	ok
41	02/02/2016		-16.9°C	ok
42	02/01/2016		-16.6°C	ok
43	01/31/2016		-15.2°C	ok
44	01/30/2016		-15.3°C	ok
45	01/29/2016		-16.2°C	ok
46	01/28/2016		-16.1°C	ok
47	01/27/2016		-16.3°C	ok
48	01/26/2016		-15.8°C	ok
49	01/25/2016		-15.5°C	ok
50	01/24/2016		-14.7°C	ok
51	01/23/2016		-14.4°C	ok
52	01/22/2016		-14.9°C	ok
53	01/21/2016		-15.1°C	ok
54	01/20/2016		-15.1°C	ok
55	01/19/2016		-15.4°C	ok
56	01/18/2016		-15.9°C	ok
57	01/17/2016		-16.0°C	ok
58	01/16/2016		-15.0°C	ok
59	01/15/2016		-15.5°C	ok
60	01/14/2016		-16.1°C	ok

Ext. sensor connection error				
Alarm ambient temp.	Status	Duration	Alarm trigger time	Signature / notes Action taken
	ok	0min		
	ok	0min		
13.6°C	ok	0min		
13.0°C	ok	0min		
14.1°C	ok	0min		
13.6°C	ok	0min		
13.7°C	ok	0min		
	ok	0min		
	ok	0min		
14.4°C	ok	0min		
13.9°C	ok	0min		
14.1°C	ok	0min		
13.6°C	ok	0min		
14.3°C	ok	0min		
13.8°C	ok	0min		
13.5°C	ok	0min		
14.1°C	ok	0min		
13.4°C	ok	0min		
13.0°C	ok	0min		
12.9°C	ok	0min		
13.1°C	ok	0min		
13.0°C	ok	0min		
13.1°C	ok	0min		
12.9°C	ok	0min		
13.8°C	ok	0min		
13.1°C	ok	0min		
13.3°C	ok	0min		
13.4°C	ok	0min		
13.1°C	ok	0min		
13.6°C	ok	0min		

Fridge Tag Example #2

Upper Alarm Limit – shows ALARM, with a maximum temp of
+11.4°C, with 3h 23min out of range with
ime 21:39h (9:39PM)



Upper alarm limit

Status	Max. temp.	Cumulative daily time above the limit	Alarm trigger time
In progress	+4.7°C	0min	
ALARM!	+16.2°C	12h 7min	00:00h
ALARM!	+11.4°C	3h 23min	21:39h
ok	+6.6°C	0min	
ok	+10.4°C	26min	

Ext. sensor connection

Status

ALARM

Continues at Midnight for 12h 7m

Fridge Tag Example #3

Upper Alarm Limit – shows ALARM, with a maximum temp of
+11.5°C, with 4h 53min out of range with an alarm triggered time 20:19h (8:10PM)

No.	Date (MM/dd/yyyy)	Events*	Average temp.	Lower alarm limit Status	Min. temp.	Duration out of range	Alarm trigger time	Alarm ambient temp.	Upper alarm limit Status	Max. temp.	Duration out of range	Alarm trigger time	Alarm ambient temp.	Ext. sensor connection error Status	Duration	Alarm trigger time	Signature / notes Action taken
31	01/31/2016		+5.3°C	ok	+4.8°C	0min			ok	+6.2°C	0min			ok	0min		
32	01/30/2016		+5.3°C	ok	+4.8°C	0min			ok	+6.1°C	0min			ok	0min		
33	01/29/2016	am	+5.5°C	ok	+4.6°C	0min			ok	+7.1°C	0min			ok	0min		
34	01/28/2016	am pm	+5.4°C	ok	+4.7°C	0min			ok	+6.6°C	0min			ok	0min		
56	01/06/2016	pm	+5.3°C	ok	+4.5°C	0min			ok	+6.5°C	0min			ok	0min		
57	01/05/2016	am	+5.5°C	ok	+4.5°C	0min			ok	+7.2°C	0min			ok	0min		
58	01/04/2016	am	+5.4°C	ok	+4.2°C	0min			ok	+7.1°C	0min			ok	0min		
59	01/03/2016		+4.7°C	ok	+4.0°C	0min			ok	+5.5°C	0min			ok	0min		
60	01/02/2016		+4.7°C	ok	+4.1°C	0min			ok	+5.5°C	0min			ok	0min		

ok	+8.0°C	0min		
ok	+5.6°C	0min		
ALARM	+11.5°C	12h 25min	00:00h	+22.6°C
ALARM	+11.5°C	4h 53min	20:10h	+22.1°C
ok	+6.6°C	0min		
ok	+6.5°C	0min		

Continues at Midnight for 12h 25m

Fridge Tag Example #4

Upper Alarm Limit – shows ALARM, with a maximum temp of
+13.0°C, with 30min out of range with an alarm triggered time 16:56h (4:56PM)

				Lower alarm limit					Upper alarm limit					Ext. sensor connection error			
No.	Date (dd.MM.yyyy)	Events*	Average temp.	Status	Min. temp.	Duration out of range	Alarm trigger time	Alarm ambient temp.	Status	Max. temp.	Duration out of range	Alarm trigger time	Alarm ambient temp.	Status	Duration	Alarm trigger time	Signature / notes
31	31.01.2016		+5.3°C	ok	+5.0°C	0min			ok	+5.7°C	0min			ok	0min		
32	30.01.2016		+5.3°C	ok	+5.0°C	0min			ok	+5.7°C	0min			ok	0min		
33	29.01.2016		+5.2°C	ok	+4.9°C	0min			ok	+5.8°C	0min			ok	0min		
34	28.01.2016		+5.2°C	ok	+4.8°C	0min			ok	+5.6°C	0min			ok	0min		
35	27.01.2016		+5.2°C	ok	+4.9°C	0min			ok	+6.2°C	0min			ok	0min		
				ok	+5.8°C	0min											
				ALARM!	+13.0°C	30min							16:56h			+27.3°C	
				ok	+5.6°C	0min											
				ok	+5.5°C	0min											
53	09.01.2016		+5.2°C	ok	+5.0°C	0min			ok	+5.6°C	0min			ok	0min		
54	08.01.2016		+5.2°C	ok	+5.0°C	0min			ok	+6.2°C	0min			ok	0min		
55	07.01.2016		+5.2°C	ok	+5.0°C	0min			ok	+5.6°C	0min			ok	0min		
56	06.01.2016		+5.2°C	ok	+4.9°C	0min			ok	+5.6°C	0min			ok	0min		
57	05.01.2016		+5.2°C	ok	+5.0°C	0min			ok	+6.4°C	0min			ok	0min		
58	04.01.2016		+5.3°C	ok	+5.1°C	0min			ok	+6.2°C	0min			ok	0min		
59	03.01.2016		+5.5°C	ok	+5.2°C	0min			ok	+5.9°C	0min			ok	0min		
60	02.01.2016		+5.5°C	ok	+5.2°C	0min			ok	+5.9°C	0min			ok	0min		

Documentation of excursion

- Best practice to use a sample 'Documentation of Temperature Troubleshooting' on MDPH website
- Keeps a record of temperature excursions available

Documentation of Temperature Troubleshooting

Practice Name : DPH Pediatrics **PIN : 55555**

Date and time of incident	Problem	Date, time, contact person spoken to at MDPH	Action Taken	Initials and date
5/4/2016 4:35pm	Maximum temps in freezer went to -8.7°C for over an hour and triggered an alarm.	5/4/2016 4:40pm Lois Ciccone	Shut freezer door and monitored temperature to ensure it returned to range. The temp returned to -15°C by 5:10pm. Per Lois at the Vaccine Unit, vaccines are ok to use.	SS 5/4/2016

Temperature Adjustment

- If a refrigerator is running on the cold side, or is slowly becoming colder, you should take action
- Never adjust the refrigerator temperature control with vaccine in unit
- Remove vaccine to another refrigerator/freezer
- Adjust temperature of unit
- Wait until you have 3 successive readings one hour apart within range before returning vaccine to the unit

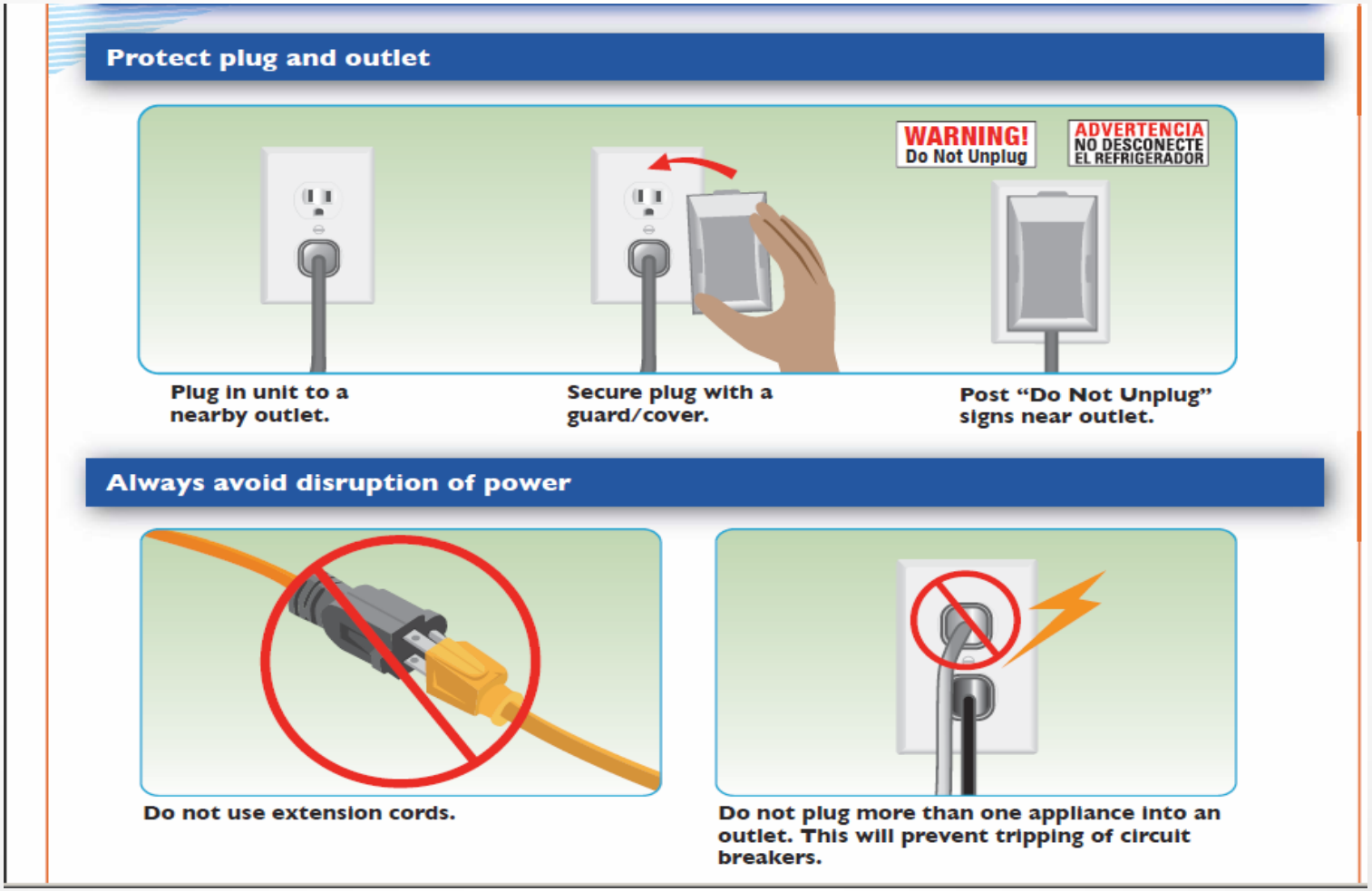
Power Failure

- If you lose power for extended period, follow your emergency plan:
  - pack vaccine
  - transport to prearranged site
  - notify MDPH Vaccine Unit, if state-supplied
- When power returns:
  - do not adjust the temperature control in unit
  - allow unit to return to proper temperature range
  - return vaccine to unit

Safeguard Power Supply

- Use a plug guard or safety-lock plug
- Place "Do Not Unplug" sign on storage unit, outlet and "Do Not Disconnect" on circuit breakers
- Consider installing a temperature alarm
- Do not use extension cords

Safeguard Power Supply



Safeguard Power Supply

Vaccine Storage & Handling Questions

- MDPH Vaccine Management Unit
  (617) 983-6828

- MDPH Division of Epidemiology and Immunization
  (888) 658-2850
  (617) 983-6800 (24x7)

- Always consult with MDPH Immunization Program before removing improperly stored state-supplied vaccine from the storage unit
  - If the temperature of the vaccine goes out of range, either too high or too low, call the MDPH Vaccine Management Unit immediately!

And thanks to you…

To all of the Medical Directors, Back-up Vaccine Coordinators, RNs, MAs, other office staff involved with immunizations at provider offices and, especially, to the Vaccine Coordinators,

Thank you for all you do to take care of vaccines and, in turn, take care of your patients and protect them from vaccine preventable diseases!

QUESTIONS?

Thank You !