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# VFC UPDATES DATA LOGGERS



# A Little Bit About Me

- Molecular Biologist
  - Vaccine Development
  - Forensics
  - GSK Quality Assurance – Hamilton, MT
- Freelance Technical Communicator
  - Technical Writer
  - Training Developer
- Vaccine Coordinator – September 2010



# VFC Updates

## Why change?



- Update Form or Process (or both)
- New (or delinquent) CDC Requirement
- Clearly Communicate Requirements
- Move Towards New Registry

# New Forms and Publications

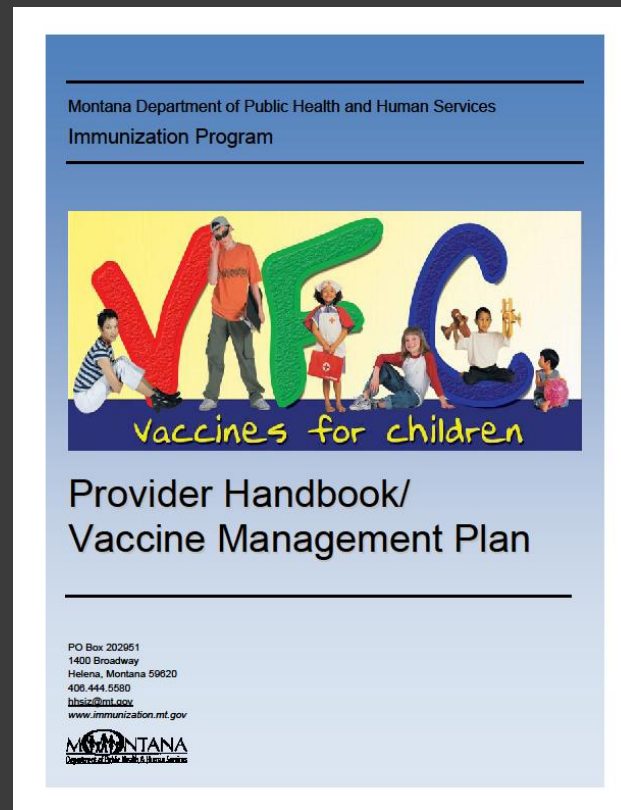
# VFC Handbook/Vaccine Management Plan

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- CDC – All providers must have a VMP
  - 2008 – Montana Vaccine Management Plan
  - “Customizable Template”
- Needed Update
- No “one-stop-shopping” reference for MT VFC
- VMP ↔ New Registry

# VFC Handbook/Vaccine Management Plan

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# VFC Handbook/Vaccine Management Plan

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- ⦿ One Document → Two Sections
  - VFC Handbook
  - Vaccine Management Plan
  
- ⦿ Works with website:  
[www.immunization.mt.gov](http://www.immunization.mt.gov)
  - Current forms with instructions (single-source)
  - Handbook/Vaccine Management Plan by section with revision dates
  - We notify → You update

# VFC Handbook/Vaccine Management Plan

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## ⦿ Features

- Table of contents
- Section #, title, revision date on footer
- Requirement checklist Section 8
- Online version with hyperlinks
- Customize VMP – Section 12
  - Fill-in → Review → Post on storage units
  - Repeat annually

# VFC Handbook/Vaccine Management Plan

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## Take Home Message

HB/VMP ↔ Website

[www.immunization.mt.gov](http://www.immunization.mt.gov)

Customize and Post Section 12

# New Forms and Publications

# Vaccine Incident Report (VIR)

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- ⦿ Instructions for responding to and documenting temperature excursions
- ⦿ Temperature Excursion – A period of time when vaccine is stored outside of the temperatures recommended by the manufacturer.
- ⦿ Why worry about temperature excursions?
  - Efficacy
  - Waste → Money
  - Time

# Vaccine Incident Report (VIR)

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- ⦿ Temperature Excursion - Ideal Response:
  - Prevention!
  - Immediate
  - Prevents use of compromised vaccine
  - Determines vaccine viability (reliable info)
  - Documents the event and actions taken
  - Prevents repeat occurrence through corrective action

# Vaccine Incident Report (VIR)



## Immunization Program

### Vaccine Incident Report

Follow the procedures below when your publicly purchased vaccine has experienced out-of-range storage temperatures. Use a separate report for each affected storage appliance.

1. Do not use or discard the affected vaccine.
2. Contact your Vaccine Coordinator or Alternate Vaccine Coordinator (if primary is unavailable).
3. Isolate the affected vaccine, mark the boxes with an "X," and post a clear "Do Not Use" sign.
4. If the situation is temporary or quickly remedied (w/in 3 hours), keep the vaccine in its original storage unit with the door closed.
5. If necessary, move the vaccine to a working storage unit or your emergency storage location. Be sure to monitor temperatures at this location.
6. Contact the Montana Immunization Program 444-5580.
7. Record the following information about the incident:

Facility Name: \_\_\_\_\_ VFC # \_\_\_\_\_

Reported by: \_\_\_\_\_ Telephone # \_\_\_\_\_ Date Reported \_\_\_\_\_

Storage Unit Involved: \_\_\_\_\_  
(Use a separate report for each affected storage appliance.)

- When was the incident discovered? Date \_\_\_\_\_ Time \_\_\_\_\_ am/pm (circle one)
- Room Temperature at time of discovery: \_\_\_\_\_ C / F
- Temperature of storage unit at time of discovery: Refrigerator \_\_\_\_\_ C / F Freezer \_\_\_\_\_ C / F  
(Record temperature for refrigerator and freezer if a combined unit.)
- Last known temperature recording prior to incident: Date \_\_\_\_\_ Time \_\_\_\_\_ am/pm (circle one)
- Temperature at last known recording: Refrigerator \_\_\_\_\_ C or F Freezer \_\_\_\_\_ C or F  
(Record temperature for refrigerator and freezer if a combined unit.)
- Time interval vaccine was exposed to out-of-range temperatures: \_\_\_\_\_ days \_\_\_\_\_ hrs \_\_\_\_\_ minutes  
(Estimate the worst case scenario based on last recorded temperatures. If using a data logger, use the graphing function to determine the exact interval.)
- Has the affected vaccine experienced previous temperature excursions? \_\_\_ Yes \_\_\_ No

8. Inventory the affected vaccine in columns 1–5 of the Vaccine Inventory Table on page 2 of this form.
9. Contact the manufacturer of the affected vaccine to determine its viability. Use the contact information on page 2. The manufacturer will need the information recorded above to determine vaccine viability. Record the information from the manufacturer in columns 6–8 of the Vaccine Inventory Table.

MT IZ VFC Form 204.1 (revised 02/01/11) Page 1 of 2

Instructions

Information about event



# Vaccine Incident Report (VIR)

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## Take Home Message

- Current VIR on website:  
[www.immunization.mt.gov](http://www.immunization.mt.gov)
- Have paper copies on hand
- Act immediately
- Follow instructions
- Call MT IZ Program 444-5580

# New Forms and Publications

# Monthly Vaccine Report

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- Submit monthly report for every month you have publicly supplied vaccine in inventory (VMP - Section 15).
- Two Options:
  - Monthly Vaccine Report
  - WIZRD Inventory Report
- New Form:
  - Updated
  - Clarified Instructions
  - Mimics New Registry Report Form

# Monthly Vaccine Report



## Monthly Vaccine Report (Public Provider)

VFC ID # \_\_\_\_\_

Report for Month \_\_\_\_\_ Year \_\_\_\_\_

Name of Facility: \_\_\_\_\_ Person Filing Report: \_\_\_\_\_ Phone: \_\_\_\_\_ Email: \_\_\_\_\_

### Instructions for completing this report:

This report must be submitted to Home IV Pharmacy by the 5<sup>th</sup> of each month and covers the previous month. Submit by FAX: (406-723-4059) or Mail: 2601 1/2 Continental, Butte, MT 59701. **If you FAX, you must also mail a copy.** Always keep a copy for your records.

Column A – VFC vaccines are listed in this column. Brand names are included where clarification is needed or where there is a choice.

Column B – Transcribe the "Doses on hand end of month" (Column H or I) from the previous month's report.

Column C – Enter doses received through orders and transfers from other providers. Do not track VFC-private stock "borrowing" on this report.

Column D – Enter doses wasted, expired, or transferred to other providers.

Column E – Enter the name and VFC# of providers with whom you transferred vaccine along with the number of doses in or out ("3 doses to Big Hill Pediatrics #133"). Be sure these doses are included in either Column C or D, depending on whether they were transferred in or out.

Column F – Add columns B and C, then subtract Column D. This gives the total doses available for administration for the month. Enter this in Column F.

Column G1-13 – Enter doses administered for the month by age. Total columns G 1-6 and enter in Column G-13 "Total doses administered."

Column H – Subtract Column G-13 ("Total doses administered") from Column F. This gives the number of doses on hand at the end of the month based on your report calculations.

Column I – Now take an actual inventory of your VFC vaccine and enter in Column I. Columns H and I should be the same. If not, re-examine your report, inventory, and charting documentation to reconcile any discrepancies.

Column J – List the lot numbers and expiration dates remaining in your VFC vaccine inventory.

Current forms can be obtained at: [www.immunization.mt.gov](http://www.immunization.mt.gov) under the VFC link.

Questions? Call or email the Montana Immunization Program 444-5580 [hhs@mt.gov](mailto:hhs@mt.gov)

### Monthly Report for VFC Vaccine

A	B	C	D	E	F	G 1-13 (Mandatory)											H	I	J			
						Doses administered during the month by age (years)																
Vaccine	Doses on hand start of month	Doses received during month (orders and transfers)	Doses transferred out, wasted or expired during month	If doses transferred in or out, indicate which provider you transferred doses to or received doses from and their VFC#.	Total doses available (B+C-D)	<1	1	2	3-4	5	6-9	10-14	15-19	20-24	25-44	45-64	65+	total doses administered	Doses on hand end of month- Calculated (F-G13)	Doses on hand end of month- Actual Inventory (H-I)	Lots/ Expiration Dates (Mandatory)	
DTaP																						
DTaP/IPV (Kinrix*)																						
DTaP/IPV/Hib (Pentacel*)																						

Instructions by column

Balance sheet

# Monthly Vaccine Report

Previous month's report  
 "Doses on hand end of month"  
 (Column I)

Missing Doses

Calculated Inventory =  
 Actual Inventory

Monthly Report for VFC Vaccine																		
A Vaccine	B Doses on hand start of month	C Doses received during month (orders and transfers)	D Doses transferred out, wasted or expired during month	E If doses transferred in or out, indicate which provider you transferred doses to or received doses from and their VFC#.	F Total doses available (B+C-D)	G 1-13 (Mandatory) Doses administered during the month by age (years)										H Doses on hand end of month- Calculated (F-G13)	I Doses on hand end of month- Actual Inventory (I=H)	J Lots/ Expiration Dates (Mandatory)
						<1	1	2	3-4	5	6-9	10-14	15-19	20-24	25-44			
DTaP																		
DTaP/IPV (Kinrix*)																		
DTaP/IPV/Hib (Pentacel*)																		

# Monthly Vaccine Report

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## Take Home Message

- Current form on website:  
[www.immunization.mt.gov](http://www.immunization.mt.gov)
- Please use it:
  - Current vaccines
  - Moves towards New Registry Vaccine Management Module
  - “Grace Period” when switching

# New Policies

# Dormitory-Style Refrigerators

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Freezer inside  
refrigerator



One external  
door

Size doesn't matter!!!

# Dorm-Style Storage Unit Policy

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- CDC:

- No - permanent storage

- Yes - temporary storage

- Definitions:

- Permanent storage is defined as that involving more than one day's supply of vaccine for longer than one daily work shift (12 hours).

- Temporary storage is defined as that where only one day's supply of vaccine is stored for one workday (no more than 12 hours). Vaccine is returned to permanent storage at the end of each day.

# Dorm-Style Storage Unit Policy

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- Montana VFC Policy:
  - No - permanent storage
  - Yes - temporary storage (grandfathered in)
- Policy Implementation
  - Memo February 3, 2011/Ref-Freezer Guide
  - Memorandum of Understanding (MOU)
  - Survey → Follow-up
  - Regional Meetings
  - Assess compliance during 2011 site visits

# Dorm-Style Storage Unit Policy

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## Take Home Message

- Do not buy dorm-style units
- If you have a dorm-style unit:
  - DO NOT USE for permanent storage.
  - Temporary storage – must have MOU
- Non-Compliance → Corrective Action

# New Policies

# Thermometers - Data Loggers

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- CDC Thermometer Requirement - Certified calibrated against NIST or ASTM standard at manufacturer's recommended frequency
  - MT IZ Program provided liquid-filled thermometers.
  - Poor documentation
  - No plan for recalibration
- Temperature Excursion Guessing Game
  - Many states require “continuously monitoring” thermometers

# MT VFC Thermometer Policy (VMP - Section 14)

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- VFC storage unit thermometers must be:
  - Certified calibrated
  - Continuously monitoring
    - Saves data. Archives for three years.
- MT IZ Program provides:
  - One Data Logger for every vaccine storage unit in the VFC Program

# What is a Data Logger?

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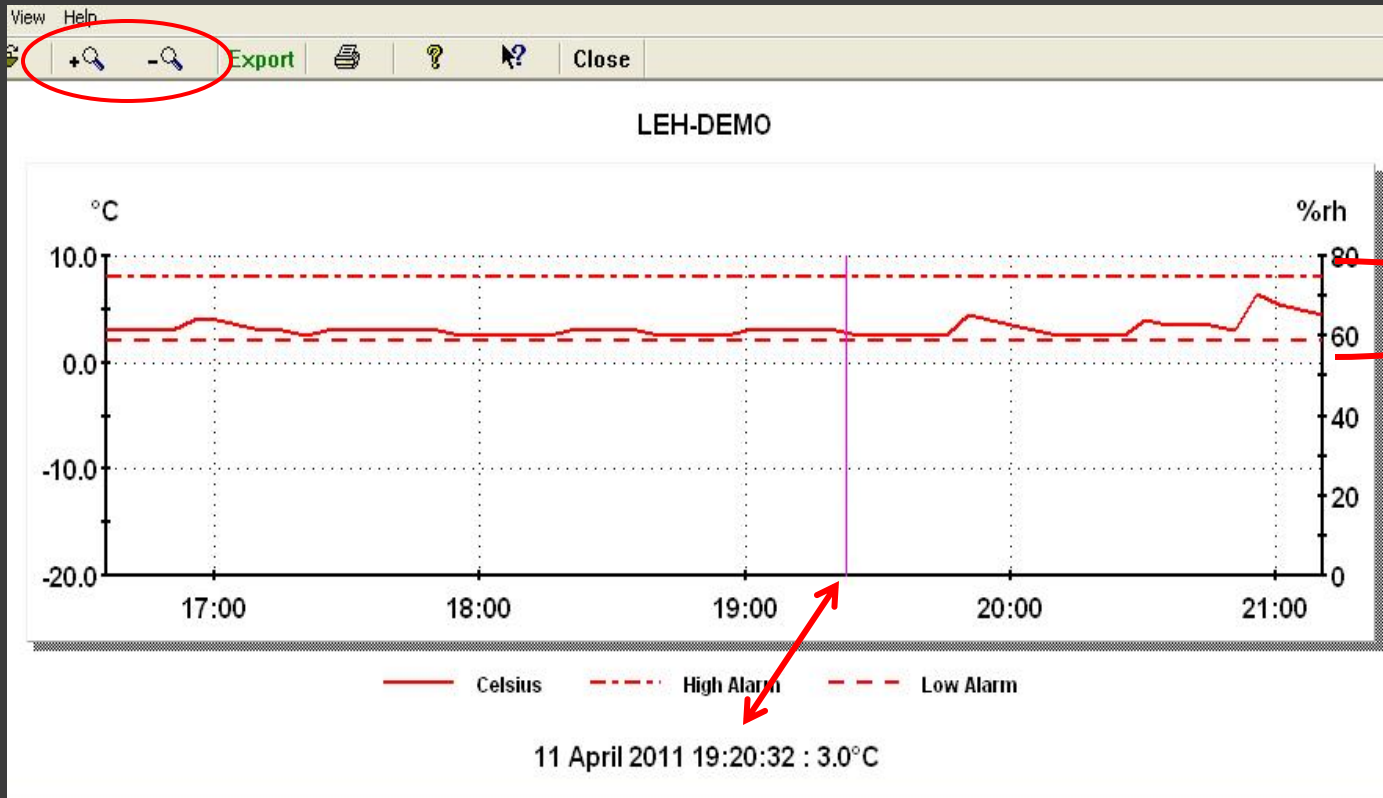


# What is a Data Logger?

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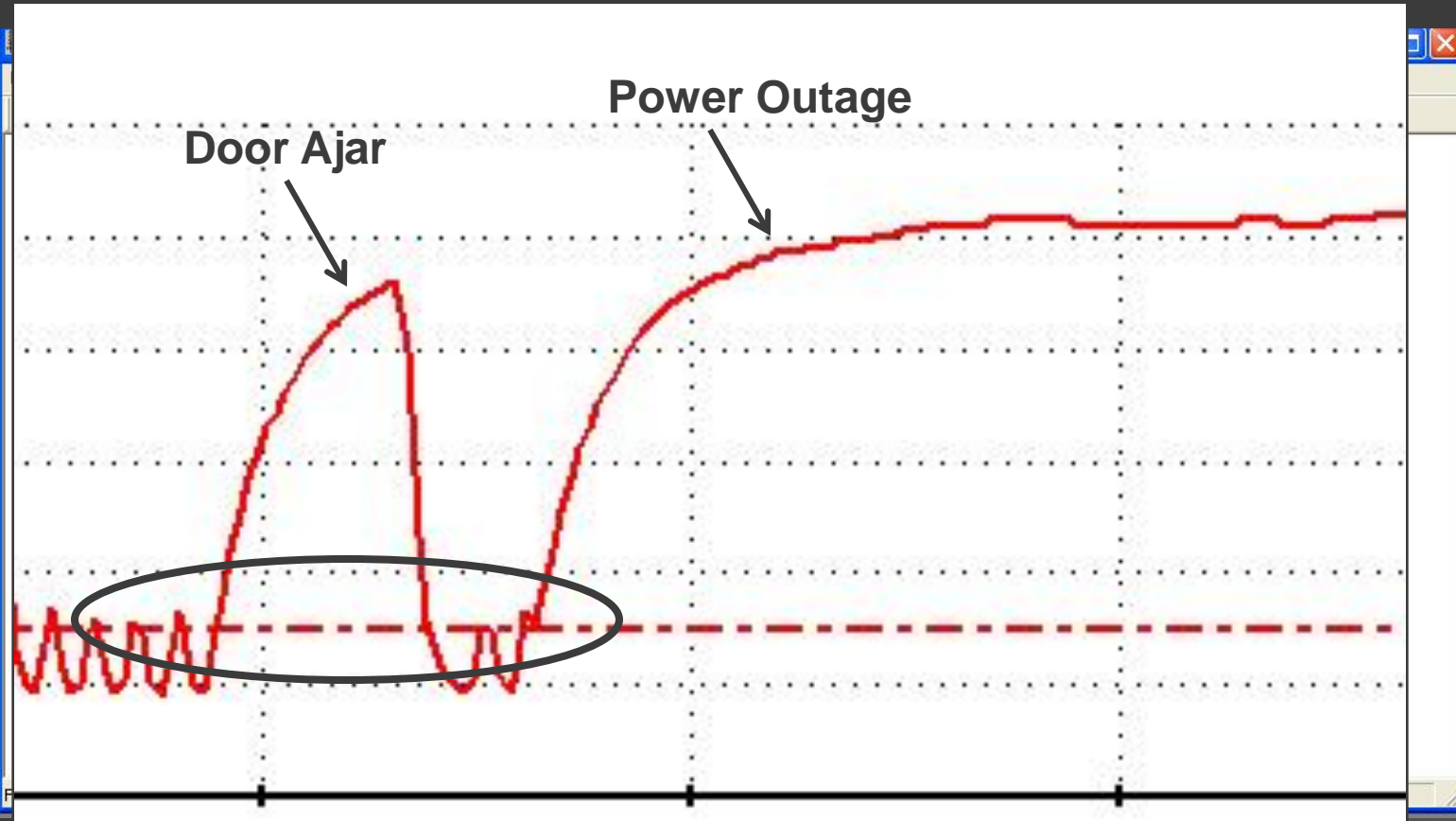


# Data Logger Data



High-Low  
Thresholds

# Data Logger Data



# Data Logger Package Deal (VMP - Section 14)

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- MT IZ Program provides:
  - One Data Logger for every vaccine storage unit in the VFC Program
    - Certified calibrated for one year
    - Extra battery
    - Acrylic stand
    - Software
  - Training/tech support/Instructions
  - Facilitate annual re-calibration

# Data Logger – Your Responsibilities (VMP – Section 14)

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- Certified calibrated, continuously monitoring thermometer → Data Logger
- Windows<sup>®</sup> - based computer
- Replacement if broken or malfunctions
- Annual re-calibration after first year (\$50/DL)
- Reliable back-up thermometer
- Routine-use:
  - Log temps/LED status twice daily (logs provided)
  - Respond to out-of-range indicator (VIR)
  - Save monthly data. Archive for three years

# Data Logger – 2011 Transition Year

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- Spring 2011 – Data Logger distribution
  - Tech support
  - Compliance and additional tech support during clinic reviews
  - Transition issues:
    - Frost-free freezer thresholds
    - Problem storage units
    - Interpreting temperature excursion data
- New Registry
  - Cold chain data required for ordering

# VFC Update-Data Logger Recap

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- New Forms and Publications
  - Handbook/Vaccine Management Plan
  - Vaccine Incident Report
  - Monthly Vaccine Report
- New Policies
  - Dormitory-Style Storage Units
  - Data Loggers

# Questions?

