Texas Department of State Health Services

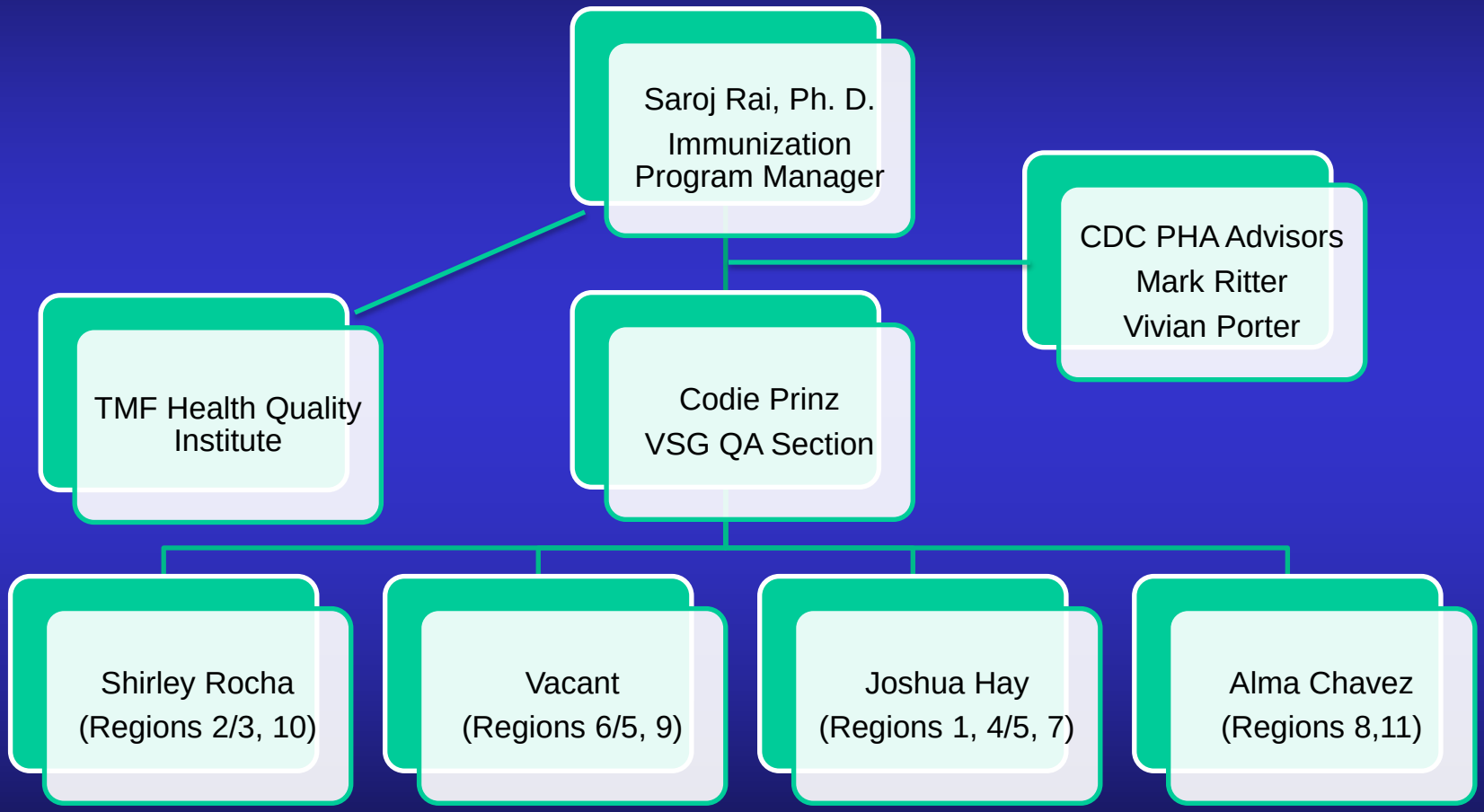
TVFC Storage and Handling Training

TEXAS Department of State Health Services

www.ImmunizeTexas.com

VACCINES Build your child's health

DSHS Immunization Branch VSG Quality Assurance Section



TEXAS Department of State Health Services

8 Principles

- Principle 1 - Do not freeze refrigerated vaccines
- Principle 2 - Store vaccines in equipment that maintains appropriate storage temperatures
- Principle 3 - Store vaccine in a temperature stable location of the storage unit
- Principle 4 - Monitor vaccine storage unit temperatures
- Principle 5 - Immediately unpack vaccine deliveries, examine and store
- Principle 6 - Remove expired vaccine from a storage unit
- Principle 7 - Provide maximum time at worst temperature when calling manufacturer about a temperature excursion
- Principle 8 - Use equipment that maintains correct temperature for transport

8 Principles Format

- The Science that was used to update guidance and policy
- Supporting facts
- VFC Requirements/Recommendations
- What Would You Do (WWYD) Scenarios
- Activities/Job Aids

National Institute of Standards & Technology Studies

- **Studies evaluated storage units under the following testing conditions:**
  - Effect of
    - loading density
    - packing style
    - door opening and closing (normal use simulation)
    - increasing room temperature
    - power outage
  - Defrost cycles
  - General stability of vial temperature & suitability of unit for maintenance of storage conditions
  - Best and worst locations storage

Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2010, NISTIR 7753
Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2009, NISTIR 7656

CDC Guidance
NIST Studies cont.

- **Evaluated thermometers:**
  - Best and worst methods of monitoring vial temperature
  - Best, mediocre and unacceptable locations for temperature sensors

- **In addition, evaluated:**
  - Data loggers
  - Effect of freezer setting on refrigerator in dual zone combination unit

Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2010, NISTIR 7753
Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2009, NISTIR 7656

Principle 1

DO NOT FREEZE REFRIGERATED VACCINES

Principle 1: Do not freeze
Supporting Facts

- Manufacturer stability data demonstrates that freezing (<32°F/0°C) most refrigerated vaccine DESTROYS them
- Visual inspection is NOT a reliable indicator of freeze damage
- Anecdotal reports suggest that freezing is the most common reason for revaccination

Picture: Vaccines for Children Program: Vulnerabilities in Vaccine Management. HHS Office of the Inspector General. June 2012

Principle 1: Do not freeze
VFC Provider Requirements

- **VFC Requirements:**
  - Report vaccine storage and handling incidents resulting in loss, reasons for loss and number of doses involved
  - Develop and implement written protocols for reporting and responding to losses
- **Recommendations – All Providers**
  - Patients who receive vaccine with reduced potency caused by inappropriate storage conditions may not be fully protected
  - Repeat vaccine dose to patients who receive compromised vaccine

VFC Operations Guide, November 2012
CDC Storage & Handling Toolkit

Principle 1: Do not freeze
WWYD – Scenario 1

Flumist is accidently placed in the freezer (-20°C) upon receipt from the distributor on Friday 3/29 and left there over the weekend. The error was not discovered until Monday 4/1 morning.

The provider leaves you a phone message on Thursday 4/4 asking if he should use the vaccine.

1. Can Flumist continue to be used?
2. What 3 things would you tell the provider?
3. What follow up would you do with the provider?

WWYD Do not freeze
Scenario 1 – Key Points

Can Flu Mist continued to be used:

What 3 things would you tell the provider:

What follow up would you do with the provider:

WWYD Do not freeze
Scenario 1 – Key Points

Can Flu Mist continued to be used:

- Flu Mist should not be used unless the manufacturer verifies that the stability data supports continued use.

What 3 things would you tell the provider:

- Contact the manufacturer.
- Do not administer doses, continue to store appropriately and quarantine.
- Document the excursion.

What follow up would you do with the provider:

- What did the manufacturer say and document?
- Is recall and revaccination needed?
- What corrective action is needed?

Principle 2

STORE VACCINES IN EQUIPMENT THAT MAINTAINS APPROPRIATE STORAGE TEMPERATURES

What kind of refrigerator should I use?

NIST
National Institute of Standards and Technology
U.S. Department of Commerce

Household, consumer-grade units		Pharmaceutical-grade units	
Freezerless	Dual-zone	Under-the-counter	Full-sized

Dual-zone unit is acceptable for refrigerated vaccine storage only – do not use freezer compartment

Principle 2: Store in correct equipment

Stand Alone Refrigerator

NIST Studies

- Can easily maintain appropriate temperatures
- Storage density and packing style did not appear to have a major impact on vaccine temperature
- In normal simulation use (door opening and closing), all thermometers attached to vials remained within range
- Drift in the refrigerator control thermometer appeared negligible

Principle 2: Store in correct equipment

Dormitory Style Refrigerator/Freezer

NIST Studies

- Unable to maintain vaccine storage temperatures
- Lacked temperature control requiring frequent adjustment to set point temperature
- Higher density packing style increased range of location-specific temperature variations
- Increase in ambient room temperature was positively correlated with increasing refrigerator temperatures
- No good storage location within the entire unit

Principle 2: Store in correct equipment

Combination Refrigerator/Freezers

NIST Studies

- Refrigerator section able to maintain appropriate storage temperatures with some precautions
- Refrigerator section withstood moderate fluctuations in ambient room temperature
- Freezer section unable to maintain frozen vaccine storage temperatures
- Even with freezer control set to “coldest” vaccines stored inside freezer section experienced thermal excursions above -15°C
- Defrost cycle caused major thermal excursions in freezer section

Principle 2: Store in correct equipment

Pharmaceutical Grade Refrigerator

NIST Studies

- Demonstrated that it can maintain appropriate storage temperatures with some precautions
- Vaccine storage density, packing style, and door opening had negligible effect on capability to maintain temperature
- Out of range temperatures occurred where there was direct contact with unit walls or near cooling vent
- Temperatures remained stable during defrost cycles

Principle 2: Store in correct equipment
Supporting Facts

- **Recommended**
  - Stand alone refrigerators and freezers can maintain appropriate storage temperatures
- **Allowable**
  - Combination units can maintain refrigerated temperatures, but their freezers may not maintain appropriate storage temperatures for frozen vaccine
- **Prohibited**
  - Dormitory style refrigerators are not capable of maintaining appropriate storage temperatures for ANY VACCINE storage

Principle 2: Store in correct equipment
VFC Provider Requirements

- **VFC Requirements:**
  - NEW- VFC Vaccines are not allowed to be stored in dormitory style refrigerators/freezers at any time

- **Recommendations- All Providers**
  - NEW- Dormitory style refrigerators/freezers, are not recommended for ANY vaccine storage
  - NEW- A stand-alone refrigerator and stand-alone freezer unit is recommended
    - Combination Units: Alternative to stand-alone units by using only refrigerator compartment but do not use top shelf or bottom to store vaccines

Principle 2: Store in correct equipment
WWYD– Scenario 3

A provider calls you on Wednesday morning following a temperature excursion in the freezer of a combination refrigerator/freezer unit on Tuesday night.

The provider bought the combination unit a year ago following immunization program recommendations.

1. What do you tell the provider to do with the frozen vaccine?
2. Would you suggest buying a separate freezer before providing more frozen vaccine?

WWYD Store in correct equipment
Scenario 3 - Key Points

What do you tell the provider to do with the frozen vaccine:

Would you suggest buying a separate freezer before providing more frozen vaccine:

WWYD Store in correct equipment
Scenario 3 - Key Points

What do you tell the provider to do with the frozen vaccine:

- Contact the manufacturer.
- Do not administer doses, continue to store appropriately and quarantine.
- Document the excursion.

Would you suggest buying a separate freezer before providing more frozen vaccine:

- If the freezer demonstrates that it can't maintain proper vaccine storage temperatures then no more frozen vaccine should be stored in it.
- You can recommend buying a separate freezer.

Principle 3

STORE VACCINE IN A TEMPERATURE STABLE LOCATION OF THE STORAGE UNIT

Principle 3: Temperature stable location

Use of Water Bottles

NIST Studies

- **Compared temperature increases inside all storage units with and without water bottles**
  - **Periodic door opening - Without water bottles, resulted in an increase of 0.2°C to 1.2°C higher than with water bottles**
  - **Refrigerator door left open a crack for 1 hr - With water bottles, resulted in longer timeframe before exceeding correct temperature limit**
  - **Simulation of power outage – With water bottles, may provide as much as an extra 3+ hours before exceeding temperature limit depending on location of the vaccine**

Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2010, NISTIR 7753
Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2009, NISTIR 7656

Principle 3: Temperature stable location
NIST Studies

- **Demonstrated that there are best and worst locations for vial storage**
  - Freezerless refrigerator - vials in bottom were last to exceed allowed maximum temperature, but vials in upper shelves experienced fastest temperature increases in simulated power outage
  - Dormitory-style refrigerator's performance was consistently unacceptable, regardless of storage location
  - Combination unit - vials placed in direct contact with glass surface or near/under cooling vent demonstrated out of range temperatures
  - Refrigerator walls and locations near cooling vents frequently demonstrated out of range temperatures

Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2010, NISTIR 7753
Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2009, NISTIR 7656

Principle 3: Temperature stable location

DUAL ZONE

NO vials touching glass shelf or directly under cooling vent = 2 to 5˚C colder

No storage in crisper drawers. Remove drawers, fill space with water bottles.

PHARMACEUTICAL

Avoid storage on top shelf- near cooling vent. First location to exceed max allowed temp during outages.

Manufacturers recommends no floor storage, but vial TC maintained at 2 to 8 ˚C throughout testing.

FREEZERLESS

1 to 2 ˚C colder than main fridge space

Best Storage Practices- Store Vaccine:

1. In the original packaging.
2. Inside designated storage trays in the center of the unit
3. At least 2-3 inches away from the walls, floor and ceiling of the storage compartment

NIST National Institute of Standards and Technology U.S. Department of Commerce

Principle 3: Temperature stable location
Supporting Facts

- All vaccines are sensitive biological substances that progressively lose their potency over time or when exposed to harmful temperatures
- Loss of potency is cumulative unless refrigerated vaccine is frozen, then it can be immediate
- Once potency is lost it can never be restored, even if returned to correct storage conditions
- Refer to NIST Guidelines for Loading Vaccines

Principle 3: Temperature stable location
VFC Provider Requirments

- **Recommendations – All Providers**
  - Store vaccines in middle of refrigerator or freezer unit away from coils, walls, floor and cold air vents
  - Never store vaccines in door or adjacent to cooling vents
  - Stabilize refrigerator and freezer temperatures with proper placement of water bottles in refrigerator; frozen packs in freezer

Principle 3: Temperature stable location
WWYD – Scenario 5

You are conducting a site visit of a very small provider who currently uses an old combination refrigerator/freezer. He only stores refrigerated vaccine.

When you look in the refrigerator, you see that flu vaccine is being stored on the refrigerator door and MMR is being stored on the floor of the unit.

1. Are these storage locations ok?
2. If not should the vaccine be discarded?
3. What should you say to this provider?

WWYD Temperature stable location
Scenario 5 – Key Points

Are these storage locations ok:

If not should the vaccine be discarded:

What should you say to this provider:

WWYD Temperature stable location
Scenario 5 – Key Points

Are these storage locations ok:

- No. NIST studies demonstrate that vaccine stored in the door or the bottom floor of the unit is at risk of temperature excursion.

If not should the vaccine be discarded:

- Do not discard the vaccine. Call the manufacturer with time at maximum temperature for further guidance.

What should you say to this provider:

- NIST studies demonstrate that these areas are risky locations to store vaccine.
- Suggest that they use water bottles in these areas.
- Evaluate if provider needs larger unit to store vaccine inventory.

Activity 3

Identifying Best and Worst Storage Locations & Methods for Loading

Directions: Identify and circle areas of each vaccine storage unit that illustrate the best and worst locations for vaccine storage.

A

B

C

D

E

F

A

Unit is a dorm-style unit which should not be used for any vaccine storage. Ice build-up affects efficiency and ability to maintain temperature.

B

Storage unit is too full. Vaccines are stored outside of original packaging.

C

Vegetable bins are empty. Water bottles are placed in the unit. Vaccines are kept in original packaging, are organized and are not touching unit walls.

D

Unit is too full. Vaccines are touching unit walls. Vaccines are stored on the unit door.

E

The unit is a dorm-style unit which should not be used for any vaccine storage. Vaccine is not organized.

F

Unit is too full.
Vaccines are touching unit walls.
Vaccines are stored outside of original packaging

Loading Vaccines

Keep vaccines in original manufacturer packaging →

Don't remove individual vials from cardboard boxes

Place vaccine boxes in plastic trays

Organize vaccines by type, VFC/private, etc. to facilitate quick retrieval and minimize time with refrigerator door open

Avoid over-filling refrigerator and hindering air circulation →

Keep vaccines in designated storage trays only

Principle 4

MONITOR VACCINE STORAGE UNIT TEMPERATURES

Principle 4: Monitor temperatures

Temperature Monitoring Devices

NIST Studies

- **Accurate temperature history reflecting actual vial temperatures is imperative to effective vaccine management**
  - Demonstrated benefits of measuring actual vial temperature rather than air temperature
  - Bio-safe glycol-encased probe most closely approximated vial temperatures
  - Digital data loggers with detachable probes provided ease of monitoring and ability to download collected data without disturbing probe

Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2010, NISTIR 7753
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Principle 4: Monitor temperatures

Temperature Monitoring Devices

NIST Studies

2013 NIST studies include:

- **Continuous temperature monitoring**
  - Buffering materials
  - Vial size
  - Probe size
- **Transport of vaccine**
  - Local transport
  - Commonly used transport containers
- **Freezers and frozen vaccine storage**
  - Conditions similar to those used for refrigerator studies

Principle 4: Monitor temperatures

Temperature Monitoring Devices

NIST Studies

- **Demonstrated that without continuous temperature monitoring system likelihood of undiscovered excursions occurring is very high**
- **Device placement is very important – must be with vaccine**

Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2010, NISTIR 7753
Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2009, NISTIR 7656

Principle 4: Monitor temperatures

Data Loggers

NIST Studies

- **Demonstrated that data loggers provide continuous temperature information**
  - Devices were downloadable providing archival data record
  - All excursions captured

  - Data logger use requires
    - training
    - willingness to change
    - and may also require computer capability,

Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2010, NISTIR 7753
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Principle 4: Monitor temperatures
Supporting Facts

- Continuous monitoring provides more reliable information on vaccine storage temperatures
- A probe in a thermal buffer (i.e. glycol, glass beads) is a more reliable measure of actual vaccine vial temperatures than a sensor that measures air
- Totally relying on an alarmed system is insufficient

Principle 4: Monitor temperatures
VFC Provider Requirements

- **VFC Requirements:**
  - Calibrated thermometer for refrigerator and freezer
    - Must have Certificate of Traceability & Calibration Testing
    - NEW- **Tested every 1-2 years or according to manufacturer recommendations**

- **Recommendations – All Providers**
  - NEW- Use digital thermometer with detachable biosafe glycol-encased probe that measures liquid temperature
  - NEW- Accuracy +/- 1°F (0.5° C)
  - NEW- Continuous data monitoring / active display min/max/current readings / placed on outside of unit door
  - NEW- Data should be stored for downloadable review

Principle 4: Monitor temperatures
VFC Provider Requirements cont.

- **Recommendations – All Providers**

Continuous Monitoring Devices:

- Alarm
- Reset button
- Memory storage of at least 4000 readings
- Does not rewrite over old data and stops recording when memory is full
- User programmable logging interval (for reading rate)

Principle 4: Monitor temperatures
WWYD – Scenario 8

Provider had a thermometer without certificate of calibration, but claimed that it was accurate.

UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899

REPORT OF CALIBRATION

International Temperature Scale of 1990

Standard Platinum Resistance Thermometer
Rosemount Model 162CE
Serial Number 4415

Submitted by:
NIST Thermometry Group
Gaithersburg, Maryland 20899 USA

This standard platinum resistance thermometer (SPRT) was calibrated with an AC bridge operating at a frequency of 30 Hz with continuous measuring currents of 1 mA and 1.414 mA. In accordance with the International Temperature Scale of 1990 (ITS-90) that was officially adopted by the Comité International des Poids et Mesures (CIPM) in September 1989, the subranges from 83.8058 K to 273.16 K and from 273.15 K to 933.473 K, with the following fixed points and their stated expanded uncertainties (k = 2), were used to calibrate the thermometer. For a detailed description of the ITS-90, see NIST TN1265, 191 pp., (1990), entitled *"Guidelines for Realizing the International Temperature Scale of 1990 (ITS-90)."* For a description of the uncertainties, see NBSIR 3318, 34 pp., (1984), entitled *"Assessment of Uncertainties of Calibration of Resistance Thermometers at the National Institute of Standards and Technology."*

Fixed Point		Temperature T_{90}(K)	Temperature t_{90}(°C)	Expanded Uncertainty where k = 2 (mK)
Ar	TP	83.8058	−189.3442	0.14
Hg	TP	234.3156	−38.8344	0.15
H_2O	TP	273.16	0.01	0.03
In	FP	505.078	231.928	0.28
Zn	FP	692.677	419.527	0.51
Al	FP	933.473	660.323	0.79

The following values were determined for the coefficients of the pertinent deviation functions of the ITS-90, as given in the attached material describing the scale. The attached tables were generated using these values.

Coefficients for Zero-Power Dissipation Calibration
a_0 = 8.90267681-4 b_0 = 6.75089798-4
a_1 = −1.64858405-4 b_1 = −6.48255605-4
c_0 = 2.29769052-6

Coefficients for 1 mA Calibration
a_0 = −1.23759986-4 b_0 = 1.06783958-1
a_1 = −1.64627895-4 b_1 = −8.45983398-4
c_1 = 1.88985840-6

The resistance of this thermometer at 273.16 K was calculated to be 25.72334 Ω at 0 mA and 25.72336 Ω at 1 mA. During calibration, the resistance at 273.16 K changed by the equivalent of 0.4 mK at 0 mA and 0.5 mK at 1 mA. This thermometer is satisfactory as a defining instrument of the ITS-90 in accordance with the criteria that $W(302.9146\ K) \geq 1.11807$ or $W(234.3156\ K) \leq 0.844235$. Measurements and analysis performed by Gregory Strouse.

For the Director,
National Institute of Standards and Technology

Dean C. Ripple
Leader, Thermometry Group
Process Measurements Division

September 14, 2007
Test No.: 275339-07
Purchase Order No.: Group Interval

67

On site visit immunization program placed thermometer with certification of calibration in the storage unit and temperatures read out of range.

1. **How do you determine when vaccines were stored inappropriately?**
2. **How do you know if a certificate is valid?**

WWYD Monitor temperatures
Scenario 8 – Key Points

How do you determine when vaccines were stored inappropriately:

How do you know if a certificate is valid :

WWYD Monitor temperatures
Scenario 8 – Key Points

How do you determine when vaccines were stored inappropriately:

- Use the worst case scenario

How do you know if a certificate is valid:

- ILAC accredited Lab
- Certificate is for the Thermometer being used
- The Certificate shows uncertainties and date of testing

Activity 4

How to Evaluate a Certificate of Calibration

1. **Statement of Traceability:** If it says "traceable to NIST" and nothing else, it is suspect. If it gives what is often called a "NIST number," it is highly suspect. These numbers may be legitimate for a calibration report from NIST but are only a reference or administrative tool and are not proof of metrological traceability to standards maintained by NIST.

2. **Calibration Due date:** This is expressly called out NOT to be included unless agreed upon by the customer. If it's included and not asked for specifically when ordering the calibration, it can be seen as a marketing tool and an imposed requirement that only that laboratory be used for recalibration.

3. **Endorsement by an accredited laboratory:** Thermometer calibration must be tested annually or according to the manufacturer's recommendation by a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body. Laboratories that have attained this accreditation meet the requirements for traceability. Check to ensure that the endorsement for an accredited calibration (the Accrediting Body Symbol which is the logo and unique laboratory code or certificate number) are included on the certificate.

4. **Level of Uncertainty:** Check to ensure that the measurement performed shows the uncertainty level. If calibration testing indicates that your thermometer is no longer accurate within, +/-1°F (+/-.5°C) then your thermometer should be replaced. Adjustments to correct the accuracy of the thermometer are not recommended.

   - Name of laboratory conducting the testing, address, date of calibration, certificate/report number, model/serial number of instrument tested.

Job Aid 4.2

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CALIBRATION REPORT FOR THERMOMETER

Report No. U173259 Page 1 of 2 SO: 123456

THE INSTRUMENT DESCRIBED BELOW WAS EXAMINED AND TESTED IN ICL'S ISO/IEC 17025 ACCREDITED CALIBRATION LABORATORY, USING NIST TRACEABLE REFERENCE STANDARDS, IN ACCORDANCE WITH ICL'S ISO/IEC 17025 CALIBRATION PROCEDURE REFERENCED BELOW. THIS CALIBRATION MEETS THE REQUIREMENTS OF ISO/IEC 17025, ANSI/NCSL Z540-1-1994, (WHICH SUPERCEDED AND REPLACED MIL-STD 45662A), AND THE ISO-9000 AND QS-9000 SERIES OF QUALITY STANDARDS.

CUSTOMER INFORMATION

SAMPLE CUSTOMER
STREET ADDRESS
CITY, STATE ZIP

PURCHASE ORDER NUMBER: NOT AVAILABLE

SUBMITTED BY: SAMPLE COMPANY

DATES

DATE REPORT ISSUED: 05-16-2011

INSTRUMENT INFORMATION

THERMOMETER ASTM 12F INSCRIPTION: LSW

MODEL: 10012F-C RANGE: -5/215F DIVISIONS: .5 °F IMMERSION: TOTAL

ENGINEERING UNITS: degrees Fahrenheit

SERIAL NUMBER: XXXX

ACCURACY TOLERANCE (maximum scale error permitted by ASTM E 1): +/- 0.25F

RESULTS OF PHYSICAL EXAMINATION

THIS INSTRUMENT WAS EXAMINED UNDER A POLARIZED LENS AND STRAINS IN THE GLASS, IF ANY, WERE JUDGED TO BE MINIMAL AND OF NO DETRIMENT TO THE FUNCTION OF THE INSTRUMENT.

THE CAPILLARY OF THIS THERMOMETER WAS EXAMINED UNDER MAGNIFICATION WITH RESULTS AS FOLLOWS: NO FOREIGN MATERIAL, MOISTURE, OR OTHER EVIDENCE OF CONTAMINATION WERE DISCOVERED. NO DISCERNABLE CAPILLARY IRREGULARITIES WERE NOTED.

IT WAS DETERMINED THAT THIS INSTRUMENT IS IN GOOD WORKING ORDER AND IS THEREFORE SUITABLE FOR CALIBRATION.

CALIBRATION PROCEDURE USED: ICL Procedure 01, which is based upon ASTM E 77, NBS Monograph 150 & NIST SP 250-23

RESULTS OF CALIBRATION

NOTE: The indications of this instrument cannot be adjusted or modified by ordinary means; accordingly, the readings given in the table below should be considered, in effect, to be both "As Found" and "As Left" readings.

TEST TEMP	READING	CORRECTION	ACCEPT LIMIT* (+ or -)	P/M/F	UNCERTAINTY
-4.00°F	-4.00°F	0.00°F	0.246°F	PASS	0.12°F
15.00°F	14.95°F	+0.05°F	0.246°F	PASS	0.12°F
32.00°F	31.95°F	+0.05°F	0.246°F	PASS	0.12°F
60.00°F	59.90°F	+0.10°F	0.246°F	PASS	0.12°F
85.00°F	84.85°F	+0.15°F	0.246°F	PASS	0.12°F
110.00°F	109.95°F	+0.05°F	0.246°F	PASS	0.12°F
135.00°F	134.95°F	+0.05°F	0.246°F	PASS	0.12°F
160.00°F	160.00°F	0.00°F	0.246°F	PASS	0.12°F
185.00°F	184.95°F	+0.05°F	0.246°F	PASS	0.12°F
210.00°F	209.90°F	+0.10°F	0.246°F	PASS	0.12°F

*ACCEPT LIMIT(s) The acceptance limit(s) shown above represent a statistical evaluation of the instrument's tolerance relative to the

SAMPLE

Principle 5

IMMEDIATELY UNPACK VACCINE DELIVERIES, EXAMINE AND STORE

Principle 5: Unpack, examine, store

Packing Style

NIST Studies

- **Demonstrated that keeping vaccines in boxes and storage trays offered thermal protection**
  - Simulated power outage - vials that exceeded maximum temperature most quickly were those that were not in trays or vaccine packaging
  - In general, vials stored inside original packaging experienced least temperature disruption during normal periodic door opening

Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2010, NISTIR 7753
Thermal Analysis of Refrigeration Systems Used for Vaccine Storage 2009, NISTIR 7656

Principle 5: Unpack, examine, store
Supporting Facts

- Manufacturer and distributer pack vaccines using qualified pack outs and containers that have been tested to maintain appropriate temperature for a given length of time up to a maximum ambient temperature

- A cold chain monitor may be used in shipping to document exposure of vaccine to out of range temperatures. The current cold chain monitor the CDC Centralized Distributor uses is not specific as to how much time or how high/low the temperature

Principle 5: Unpack, examine, store
VFC Provider Requirements

- **VFC requirements:**
  - Open packages immediately, check temperature monitor, inspect vaccine, compare vaccine received with packing list, store at appropriate temperatures
  - Contact the CDC Centralized Distributor immediately by phone if shipment has been compromised, temperature monitors are out of range or warm indicator activated
- **Recommendations – All Providers**
  - Arrange deliveries only when vaccine coordinator (or alternate) will be available
  - Examine container and content for signs of physical damage
  - Check expiration dates

Principle 5: Unpack, examine, store
VFC Provider Requirements

- **Recommendations – All Providers**
  - Check that vaccine matches ordered quantity and has correct type of diluent
  - Record arrival of vaccine and diluent in Vaccine Stock Records
  - All staff who accept vaccine shipments should be aware of need for immediate attention to shipment

Principle 6

REMOVE EXPIRED VACCINE FROM A STORAGE UNIT

Principle 6: Remove expired vaccine
Supporting Facts

- Good inventory management includes identification of soon to expire vaccine and diluent
- Move vaccine with the soonest expiration date to the front of the storage unit and mark it to be used first
- If expired vaccine is administered, the dose should not be counted as valid

Principle 6: Remove expired vaccine
VFC Provider Requirements

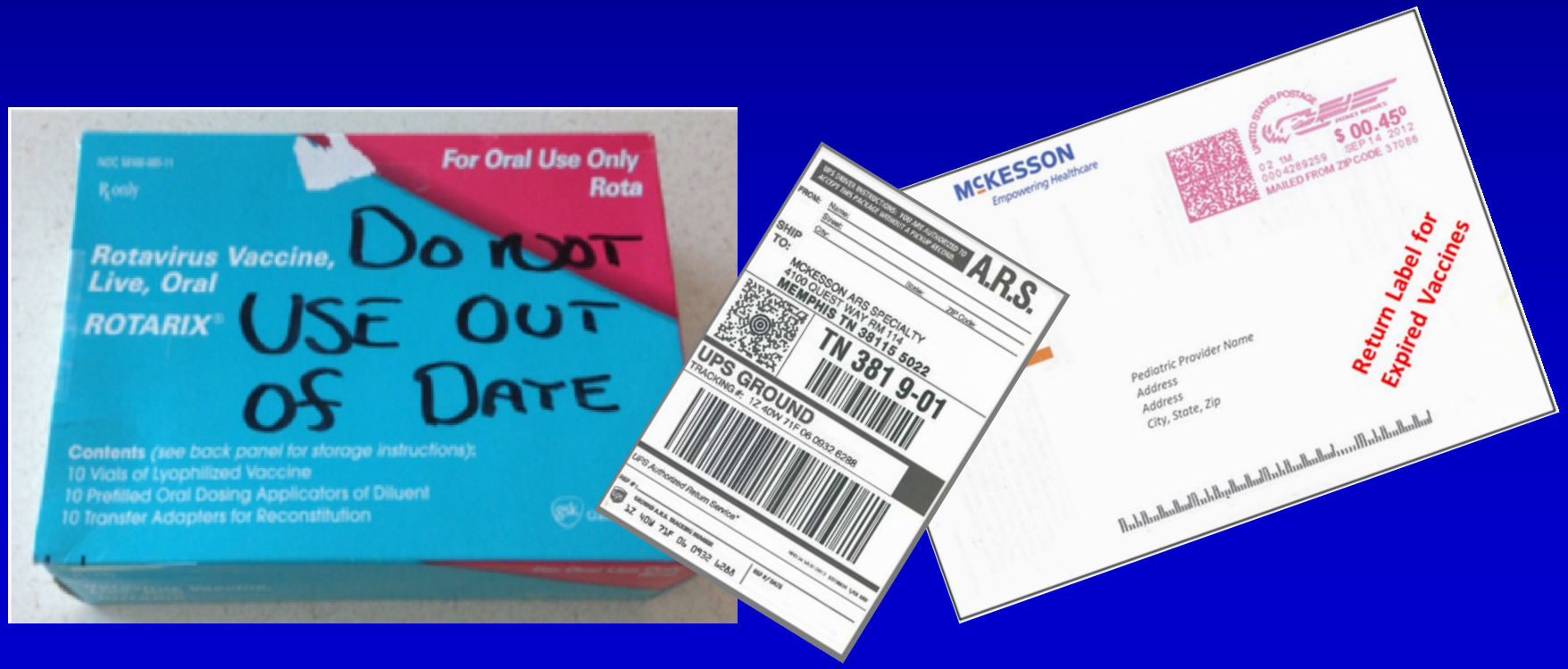
- **VFC Requirements – Provider Must:**
  - Develop and maintain complete, accurate and separate stock records
  - Notify immunization program of any vaccine soon to expire
  - Remove expired vaccine from storage unit to prevent inadvertent administration
  - Return, as directed by the immunization program, all expired publically purchased vaccine within six months
  - Transfer vaccine only with the approval of the immunization program

Principle 6: Remove expired vaccine
VFC Provider Requirements cont.

- **Recommendations – All Providers**
  - Rotate and store vaccine with soonest to expire in front
  - Never administer expired vaccine or diluent
  - Mark each multidose vial with the date it was first opened (BUD)
  - Contact the vaccine manufacturer or immunization program for disposal of expired/wasted vaccine

Principle 6: Remove expired vaccine Return Process

- **Send returns within six months after expiration/spoilage date**
  Required in FOA
- **If provider has not received label with in 7 days contact customer service at the CDC Centralized Distributor**
- **Products with Multiple NDCs, use NDC on outer box**



Principle 6: Remove expired vaccine
WWYD – Scenario 11

During a site visit you find vaccines stored in the refrigerator mixed together in bins.

Multiple vials with different expiration dates and lot numbers are mixed together.

1. How do you identify the root cause of the problem, correct it and ensure it doesn't happen again?

Principle 6: Remove expired vaccine
Scenario 11 - Key Points

Identify root cause:

Correct it:

Ensuring it doesn't happen again:

Principle 6: Remove expired vaccine
Scenario 11 - Key Points

Identify root cause:

- Ask the provider questions related to the most common causes of this problem.
  - i.e. Does the provider realize they have expired vaccine?
  - i.e. Does the provider order too much stock?

Correct it:

- Once you have identified the causes, discuss corrective measures with provider.
  - i.e. Does the provider enter all inventory correctly into EVI.

Ensuring it doesn't happen again:

- Follow-up with provider on corrective actions.
  - i.e. Work with provider before placing next order.

Activity 6.1

Matching game- Expiration date

Directions: Examine the pictures and match them according to correct expiration date.

a) Vaccine Vial #_____ has an expiration date of May 1, 2013

b) Vaccine vial # _____ has an expiration date of May 25, 2013

c) Vaccine vial # _____ has an expiration date of May 1, 2014

Vaccine Vial #1

Vaccine Vial #2

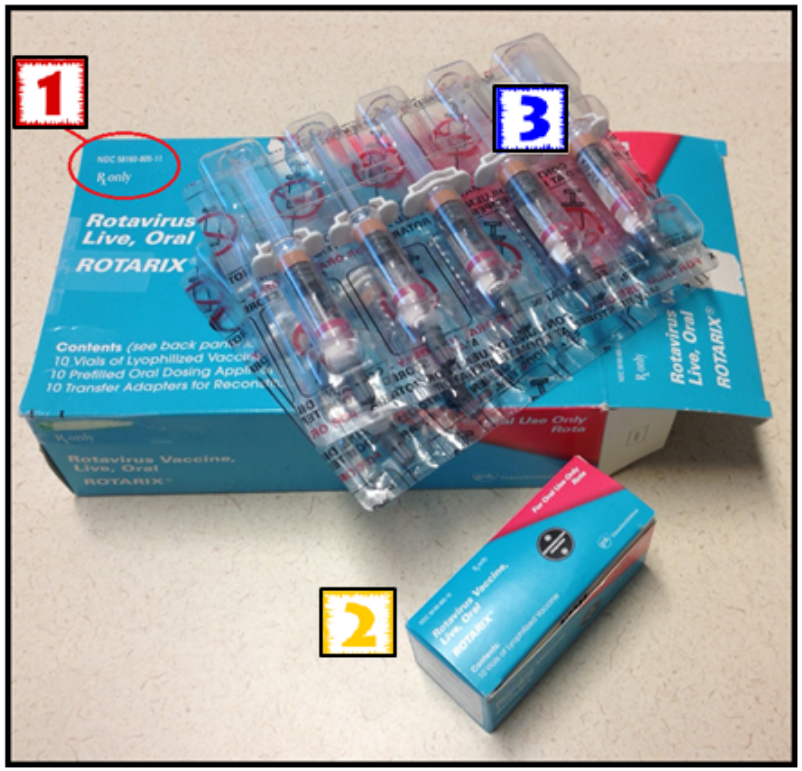
Vaccine Vial #3

Activity 6.3

Example - Products With Multiple NDCs - Example

GSK - ROTARIX

1	Main Box	NDC: 58160-0805-11	Lot: A41CA734A	Expiration: 5/9/10
2	Lyophilized Vaccine Box	NDC: 58160-0805-10	Lot: A41FA734A	Expiration: 5/9/10
3	Diluent Syringes Pack	NDC: 58160-0805-02	Lot: A41DA734A	Expiration: 6/14/11



The only NDC that can be used to order, to report inventory, or to submit vaccine returns is the one listed on the CDC contract. Using the example above, NDC 58160-0805-11 appears on the outside of the main box of Rotarix, and this is the number that is listed on the CDC contract. The Lyophilized vaccine vials box, NDC is 58160-0805-10, and the Packet of Diluent Syringes, NDC is 58160-0805-02. The number used when placing vaccine orders, reporting inventory and submitting vaccine returns is NDC 58160-0805-11 Which is listed on the outside of the Main box.

Job Aid 6.1

NONVIABLE VACCINE RETURNS

What NOT to Return to McKesson

The following items should *NEVER* be returned to McKesson:

- Used syringes, with or without needles;
- Broken vials;
- Wasted products such as a syringe that was drawn up but not used;
- Any multidose vial from which some doses have been withdrawn;
- IG, HBIG, PPD;
- Diluent (expired or not expired); or
- Private-purchased vaccine.

The items listed above should be disposed of according to usual medical biosafety procedures, and according to your immunization program's procedures.

What Should be Returned to McKesson

The following items should be returned to McKesson:

- Spoiled or expired product in its original vial or manufacturer pre-filled syringe.
- Unused manufacturer pre-filled syringes with an NDC printed on them.

Federal excise tax (FET) credits can only be processed for unopened vials and for unopened manufacturer pre-filled syringes. Returns of product other than these are not eligible for FET credit.

Principle 7

PROVIDE MAXIMUM TIME AT WORST TEMPERATURE WHEN CALLING MANUFACTURER ABOUT A TEMPERATURE EXCURSION

Principle 7: Maximum time/ worst temp Supporting Facts

- Manufacturers' stability data is based on vaccine exposure at length of time at certain temperatures
- Always calculate based on worst case scenario unless you have exact time/temperature information
- Manufacturers guidance supports or does not support continued use

Principle 7: Maximum time/ worst temp
VFC Provider Requirements

- **VFC Requirements:**
  - Provider should immediately notify immunization program and follow guidance given
  - Provider should document incident and corrective action
  - Provider should develop and implement written protocols for reporting

Principle 7: Maximum time/ worst temp
VFC Provider Requirements cont.

- **Recommendations – All Providers**
  - Separate potentially compromised vaccine from viable
  - Continue to store under appropriate temperature conditions
  - Label “do not use”
  - Contact immunization program and/or vaccine manufacturer
  - Document incident
  - Remove wasted/spoiled vaccine from storage units
  - Take action to correct improper storage conditions

Principle 7: Maximum time/ worst temp
WWYD – Scenario 14

The provider staff has been diligently logging refrigerator and freezer temperatures twice daily.

Unfortunately the staff has logged temperatures that were out of range on multiple occasions without action taken to correct or call the immunization program for guidance.

1. What steps do you tell the provider to take immediately?
2. Is it ok for an immunization program to use information from the manufacturer as guidance for future temperature excursions?

Principle 7: Maximum time/ worst temp
Scenario 14 – Key Points

What steps do you tell the provider to take immediately:

Is it ok for an immunization program to use information from the manufacturer as guidance for future temperature excursions:

Principle 7: Maximum time/ worst temp
Scenario 14 – Key Points

What steps do you tell the provider to take immediately:

- Quarantine vaccine and label "Do Not Use" until a determination can be made if vaccine is viable.
- Review temperature logs to determine maximum time at worst temperatures.
- Call the manufacturer for guidance.
- Plan for revaccination if necessary.

Is it ok for an immunization program to use information from the manufacturer as guidance for future temperature excursions:

- No. Every temperature excursion requires contact with the manufacturer for guidance on use.

Principle 8

USE EQUIPMENT THAT MAINTAINS CORRECT TEMPERATURE FOR TRANSPORT

Principle 8: Transport equipment Supporting Facts

- Improper packing of vaccine for transport is as risky as storage unit failure
- What is ok for transport may not be ok for temporary storage
- Permanent and temporary storage units have the same requirements for vaccine storage
- Manufacturers do not support reuse of their containers and packing material for vaccine transport

Principle 8: Transport equipment
VFC Provider Requirements

- **VFC Requirements:**
  - Provider should develop emergency vaccine storage & handling plan including what to do in event of refrigerator/freezer malfunction, power failure, natural disaster or other emergencies
  - Awardees are responsible for redistribution of short dated vaccines to high-volume providers when feasible and only if cold chain assured
- **Recommendations – All Providers**
  - The only way to assure that vaccine has been transported properly is monitor temperatures during transport
  - Vaccines should be delivered directly to off site facility
  - Cold chain should be assured even in emergency transport

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Principle 8: Transport equipment
VFC Provider Requirements cont.

- **Recommendations – All Providers**
  - If vaccine must be transported to off site clinic, amount should be limited to workday
  - Do not transport vaccine in car trunk
  - Unpack and store vaccine at off site clinic in appropriate equipment that maintains correct temperature

Principle 8: Transport equipment
WWYD – Scenario 16

During a surprise visit to a clinic, you find that approximately 50 doses of flu vaccine have been pre-drawn from the vials.

These pre-drawn syringes are being stored in a 'beat up' thin walled Styrofoam cooler with frozen ice packs. The syringes are sitting directly on the ice packs. The clinic has no thermometer in the cooler or anywhere in the facility.

1. Do you let the clinic continue?
2. Do you make any immediate changes, if so, what?
3. How would you guide the provider to better storage equipment?

Principle 8: Transport equipment
Scenario 16 – Key Points

Do you let the clinic continue:

Do you make any immediate changes:

How would you guide provider to better storage equipment- recommend they have a qualified container and pack-out for transport:

Principle 8: Transport equipment
Scenario 16 – Key Points

Do you let the clinic continue:

- Only if they have vials that have been stored appropriately and can be used.

Do you make any immediate changes:

- Yes- quarantine 50 pre-drawn doses until it can be determined if they are appropriate to use.
- Determine if anyone has been vaccinated with potentially compromised vaccine.

How would you guide provider to better storage equipment- recommend they have a qualified container and pack-out for transport:

- Store vaccine in appropriate refrigerator at clinic site.

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