

# GUIDELINES SMALLPOX for VACCINE PACKING SHIPPING &

#### DISCLAIMER

The use of proprietary names and description of specific manufacturers' products does not imply endorsement by the Centers for Disease Control and Prevention or the U.S. Department of Health and Human Services.

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## I. INTRODUCTION

Vaccines protect children and adults from potentially disabling and sometimes fatal diseases. If vaccines are improperly handled, they can lose their potency and must be replaced. Replacing vaccines can be costly — a shipment of vaccines can be worth hundreds, thousands or tens of thousands of dollars. It can also be costly to the providers' confidence in having properly immunized patients, and the patients' trust of the provider and of vaccines.

Every site that ships smallpox vaccines and their diluents should have its own standard operating procedures (SOPs), which describe procedures, training, supervision and record keeping to ensure continuous quality assurance year after year. In order to help you develop your procedures, the National Immunization Program of the Centers for Disease Control and Prevention has prepared the following guidelines for smallpox vaccine packing and shipping. These guidelines are based in part on CDC's research on different shipping and handling methods under strenuous test conditions. These guidelines are not intended to be rules and regulations. They are suggestions written primarily for personnel who pack and ship vaccines.

If you desire additional information on shipping and shipping materials, contact the National Immunization Program at CDC, at the following address:

Attention: Program Support Branch, Immunization Services Division Mailstop E–52, 1600 Clifton Road Atlanta, Georgia 30333 Telephone: (404) 639-8222

### 2. PROTECTING SMALLPOX VACCINES & DILUENT

The individual smallpox vaccine vial, the appropriate amount of reconstituting diluent in a syringe, and the appropriate number of bifurcated needles for administering the vaccine are usually combined ("kitted") as a single packet ("kit"). As needed, one or more "kits" is then packed and shipped to a designated receiver (clinic).

Smallpox vaccine should always be protected from heat, and should never be frozen.

#### Diluents should not be frozen.

Smallpox vaccine must be kept at appropriate temperatures to retain effectiveness. There are two major problems in storing and handling vaccines which can rapidly reduce their potency: either 1) freezing vaccines that should not be frozen, or 2) letting infectious (live) vaccines warm.

Smallpox vaccine, like DTaP, Hep A, Hep B, Hib, PCV and IPV, should never be frozen and should be kept between  $2^{\circ}$ -  $8^{\circ}$ C ( $36^{\circ}$  -  $46^{\circ}$ F)

#### THE "COLD CHAIN"

Keeping vaccines at the proper temperature at all times is called **maintaining the cold chain**. The cold chain starts at the manufacturer, and continues until the vaccine is used at the clinic or physician's office. Remember that it is as important to keep smallpox vaccine from freezing as it is to keep other vaccines from getting too warm. It's up to you to see that the "cold chain" isn't broken.

**Cold storage unit monitors** should have their temperatures certified annually against reference thermometers. Storage temperatures should be maintained between  $2^{\circ}-8^{\circ}C$  ( $36^{\circ}-46^{\circ}F$ ) for smallpox and other non-frozen vaccines. Since, in any 24-hour period, the temperature in the refrigerator will often rise or fall a few degrees, it is a

good idea to set the temperature at mid-range, about  $5^{\circ}$ C (40°F). You need a continuous temperature monitor that gives a visual record of the temperature fluctuations in the refrigerator (Figure 1).

An example of a temperature chart is shown on the next page. You will usually need to change the graph paper weekly. (Digital monitors that record data directly into a computer database are also available.) You should keep the temperature records for three years to prove that your refrigerator performed correctly over time.



Figure I A continuous temperature monitor



This sample chart shows the evenness of temperatures in a cold room during one week. Note the temperature is set at mid-range, about 5°C (40°F).

Consider a security system for the cold unit which will give a local and a remote warning if there are problems with the power or temperature (Figure 2). There should be a regular, and a back-up, alarm in distribution centers where the smallpox vaccine is stored. Such an alarm system must alert a guard, or call a certain phone number in case of a power failure or temperature problem. Be sure everyone knows how the system works, and how to reach someone responsible for the vaccines. It's correct procedure to have a written emergency plan ("Disaster Recovery Plan") posted, so staff know what to do if the power is out in the cold facility or there is a mechanical failure.

All deviations from normal temperatures or procedures should be reported in writing to supervisors and managers, and any responses taken should be recorded, also.



**Figure 2** An alarm system that calls you or a guard if there is a temperature malfunction.

Other tips are:

- Have a back-up generator in case of a power failure (Figure 3). Routine testing (weekly) assures the generator will work if needed. Critical spare parts should be available on demand for rapid repairs.
- After installing or repairing a refrigerator, allow time (~ 72 hours) for the temperature to stabilize before loading vaccines into it.

Your vaccine storage area, or cold facility, should be physically secure at all times. It's a good idea to keep the vaccine facility locked. A designated person, and a back-up person, should have access to the facility. A "Restricted to Authorized Personnel" sign may be helpful. (See **Appendix I** for Vaccine Do's.)



**Figure 3** A back-up generator takes over if the power fails. However, it should be tested and serviced regularly so that it will start when you need it.

# 3. SHIPPING MATERIALS

#### SHIPPING BOXES

Boxes should be sturdy and the right size for shipping the amount of vaccines needed. It's a good idea to have several sizes of insulated boxes on hand (Figure 4). You might code those sizes (e.g., A, B, C) and note that size on the shipping label. That way, if a box is lost in transit, you and the shipping company will know which size box you're looking for.

#### INSULATION

There are a number of ways to insulate your vaccine shipment. Types of insulation are:

- Molded polystyrene boxes which may be shipped inside a cardboard box. (See Figure 5.)
- Isocyanurate panels of foil and plastic with mitered corners inside a cardboard box. These have the advantage of folding flat for storage. (See Figure 6.)
- Polyurethane foam molded between cardboard formers (may be damaged by water. See Figure 7.) Plastic-coated boxes are more durable, but more expensive.

The insulating quality ("R Value") depends on the material and its thickness. Polystyrene boxes with walls approximately 2 inches thick, or isocyanurate panels approximately I inch thick, may provide a suitable balance between price and performance.



Figure 4 Various sized boxes for vaccine shipping.



**Figure 5** Expanded polystyrene box inside a cardboard box.



**Figure 6** Isocyanurate panels covered with foil and plastic, having mitered corners..



Figure 7 Polyurethane foam between cardboard formers.

#### FILLERS

Fillers are used in empty spaces to prevent shifting of vaccines and cold packs during shipment. They do not provide reliable insulation.

Fillers include:

- Brown packing paper. CDC tested 2-ply layers of crumpled brown paper; one ply was a "30-lb" face, the second ply was a "50-lb" face (Figure 8).
- Styrofoam pellets or "peanuts" or bubble wrap or similar materials (Figure 9).

Fillers are also used to separate frozen cold packs from the vaccines to prevent freezing.



Figure 8 Paper filler which has been crumpled before use.



Figure 9 Styrofoam "peanuts" are also used as filler.

#### COLD PACKS AND COOL PACKS

To maintain the cold chain when shipping vaccines, a cold source (or sometimes a "cool" source) is needed. Cold (or cool) sources are:

- Permanently sealed, thin-walled "gel packs" or "blue-ice." These can be reused, but may leak slightly if damaged. They are flexible when not frozen. (See Figure 10)
- Capped plastic bottles filled with a frozen liquid (water or chemical). Those tested by the World Health Organization (WHO) have special sealing plugs and caps that do not leak, except under exceptional conditions. These bottles can be emptied and refilled. (See Figure 11)

In CDC's tests, the pac performance of gel packs and bottles was similar on a weight to weight basis. Gel packs (or blue-ice) are usually kept in a freezer until they are ready to be included in a shipment. For conditions that need frozen cold packs, it's best that they are "warmed" at room temperature until they are at about  $-5^{\circ}C$  (23°F).

This may take 15 minutes or more, depending on how cold the packs are to begin with, and how they are placed for warming. cold packs in a special freezer at  $-5^{\circ}C$  (23°F) might be helpful in some facilities.

The choice of cold pack is best determined by the convenience of fit into the shipping package; for example, which size is easiest to use.\*

\* In CDC's tests, a single 24 oz. pack covered the top or bottom of a "small" box (about 5"x6"), and 4 packs completely covered the top or bottom of a "large" box (about 12" square).



**Figure 11** WHO-tested, thick-walled plastic bottles with leak-proof caps.



Figure 10 Permanently sealed, thin-walled "gel packs."

Warming will be quicker when the frozen packs are separated from each other with good circulation of room temperature air than if they are stacked together. For simplicity and consistency, freezing

#### **TEMPERATURE MONITORS**

There are a number of monitors that can measure the temperature inside your packages. You may consider including at least one heat indicator and one cold indicator in every box, with instructions on how to interpret them. More monitors may be useful to measure temperatures in different places inside larger boxes.

CDC tested the following monitors:

- Time/temperature tags which monitor temperatures warmer than 10°C (50°F). After pulling the activation tab, an irreversible blue dye is released in the windows as they are exposed to temperatures warmer than 10°C(50°F). The more blue windows, the higher the temperature reached inside the box or the longer the time at temperatures warmer than 10°C (50°F) (Figure 12).
- Color-change monitors, which detect exposure to temperatures colder than 0°C (32°F), by releasing a red dye marker into a visible bulb. Particularly useful in very cold weather (Figure 13).
- Analog disposable recording temperature monitors which produce linear strip charts over a 4day period. They may be appropriate for large, expensive shipments (Figure 14). (Electronic, digital recording thermometers are available, also.)

(See **Appendix 2A** for instructions on using monitors, and **Appendix 2B** for instructions on reading monitors when received in vaccine shipments.)



**Figure 12** The windows in a time/temperature tag turn blue as the temperature inside the package reaches more than  $10^{\circ}$ C ( $50^{\circ}$ F).







**Figure 14** Analog disposable recording temperature monitors which use a battery powered motor to pull a strip chart. The chart is obtained by breaking open the recorder box.

#### **INSERTS/INFORMATION**

A packing slip with the contents and a telephone number to call with vaccine inquiries should be included.

#### SEALERS

To assure that the package is tightly sealed and that the vaccines don't spill or shift during shipping, seal the packages well with tape or strapping.

Sealers include:

- Self-adhesive tape which can be used to seal all lids very tightly on polystyrene containers and to seal the top flaps on outer cardboard boxes of all packages.
- Plastic strapping machines are also used to seal outer boxes.

#### LABELS

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After the boxes are sealed, it is important to mark the boxes as clearly as possible to designate the contents – valuable and fragile vaccines. A variety of stickers are available. (See **Appendix 3** for samples of labels.)

#### **COMMERCIAL CARRIERS**

It is important that commercial carriers charged with getting your vaccines to the provider fully understand their responsibility. The more clearly you can specify your requirements and work with the contractor(s) of choice, the better the results, and the more likely you and the recipient will be satisfied.

(See **Appendices 4 and 5** for a list of packing materials you will need and examples of sources.)

## 4. THE PACKING PROCESS

#### ESTABLISHING A ROUTINE — THE NEED FOR STANDARD OPERATING PROCEDURES

It is important to establish a routine, systematic process for handling smallpox vaccine orders. Many facilities find that an "assembly line-type" procedure works best. It helps avoid confusion, protects the cold chain, and helps ensure that the order is filled properly.

We suggest that only one box be packed at a time at each packing station. (See **Appendix 6** for a sample procedure. You may want to adapt this system to fit your needs, or you may want to devise a totally different program.)

Each facility should develop its own standard operating procedures (SOPs), covering every aspect of work; receiving, storing, and packing and shipping smallpox vaccines. You may want to test various materials and packing configurations to see what works best for your situation. The following "Howto's" are examples of packing based on tests by CDC.

In order to comply with good manufacturing practices, written SOPs should also exist, and be followed, for training and monitoring staff performing the work. Otherwise, there can be no assurance that procedures will continue to be followed, and problems identified, reported, and corrected.

#### COOLING REQUIREMENTS FOR SMALLPOX VACCINE SHIPMENTS

#### Smallpox vaccine should never be frozen.

Cold packs (i.e., # 0°C, 32°F) should be used to keep smallpox vaccine temperature at  $2^{\circ}$ -  $8^{\circ}$ C (36° - 46°F) during shipping to ensure potency.

# Temperature monitors should normally be used.

To keep vaccines from freezing while also keeping them from getting too warm during shipping, you can: 1) vary the temperature of the "cold" packs, and/or 2) vary the number of "cold" packs used, based on the outside temperature. The quality of the insulation will also affect the internal package temperatures. When using boxes of similar quality as those tested by CDC, the following guidelines are suggested.

#### Example I — "hot weather"

In "hot weather," temperatures warmer than  $25^{\circ}$ C ( $75^{\circ}$ F), use enough cold packs to fully cover two or more faces (e.g., top and bottom or front and back) of the inside of the package. These "cold" packs should be at 0°C ( $32^{\circ}$ F). This should maintain internal temperatures for up to 48 hours.

#### Example 2 — "temperate weather"

In "temperate weather,"  $0^{\circ} - 24^{\circ}C$  ( $32^{\circ} - 75^{\circ}F$ ), either pack vaccines as you would for hot conditions, with the "cool" packs at  $-5^{\circ}C$  ( $23^{\circ}F$ ), or use enough cool packs to fully cover four sides of the inside of the package.

These "cool" packs should be at  $+5^{\circ}C$  (41°F) for short-term delivery of less than 24 hours.

#### Example 3 — "cold weather"

In "cold weather," vaccine packages may be exposed to temperatures colder than 0°C (32°F) outside, but also, to temperatures of 24°C (75°F) in a heated indoor area. There is a significant risk that vaccines will freeze when left in unheated locations outdoors. Therefore, use enough cool packs to fully cover all six sides of the inside of the package. These "cool" packs may be at +10°C (50°F) for short-term delivery up to 24 hours. Protection against freezing during extended outdoor exposure can be obtained with "cool" packs initially at 15°– 20°C (59°– 68°F). (See **Appendix 7** for a climate chart.)

#### HOW TO PACK SHIPMENTS OF NON-FROZEN VACCINES

#### Example I — small box

(Inside dimensions about 6"x6"x8") For a small shipment of smallpox vaccine and diluent:

- put one 24 oz (600 gm) cold pack on the bottom (See Figure 15)
- use 4 layers of crumpled 2-ply brown paper or bubble wrap to separate the cold packs from the vaccine kits at the bottom of the package (See Figure 16)
- put the vaccine kits in the center of the vaccine load and close to the cold packs in order to maintain the desired internal temperature range (See Figure 17)
- if the vaccine has been reconstituted, ship the vial inside the stability block. Place additional brown paper around the stability block to assure the vaccine does not tip over. Ship the bifurcated needles with the vaccine.
- place a heat monitor closest to the vaccine (but away from the cold packs) so the receiver can tell if the temperature stayed within the acceptable range during transit
- place a freezing temperature indicator near the outside of the vaccines in winter, or near a cold pack (summer and winter)
- use more brown paper or bubble wrap on top of the vaccines (See Figure 18)
- put one "cold" pack on the top
- add filler, if needed

- enclose a packing list
- seal the box and add labels
- store in the cold unit when there will be a delay (more than 4 hours), or at room temperature (less than 4 hour delay), until the commercial carrier picks it up



Figure 15 Put one cold pack on the bottom of a small box.



**Figure 16** Put crumpled brown paper between cold packs and the vaccines.



**Figure 17** Put the vaccines close to the cold pack. Put a heat monitor on top of the vaccines, but not adjacent to the cold pack.

#### Example 2 — medium box

(Inside dimensions about 10"x10"x7") For a medium shipment of smallpox vaccine and diluent:

- put one 24 oz (600 gm) cold pack on each of two facing sides (See Figure 19)
- use 4 layers of crumpled 2-ply brown paper to separate the vaccines from the bottom and all sides of the box (See Figure 20)
- put the vaccine at the "cold" sides or near the top in order to maintain the desired internal temperature range (See Figure 21)
- place a heat monitor close to the vaccine (but away from the cold packs) so the receiver can tell if the temperature stayed within the acceptable range during transit
- place a freezing temperature indicator near the outside of the vaccines in winter, or near a cold pack (summer and winter).
- use more crumpled brown paper (4 layers of 2ply) or bubble wrap on top of the vaccines
- put one "cold" pack on the top
- add filler, if needed
- enclose a packing list
- seal the box and add labels
- store in the cold unit or in normal ambient temperature until the commercial carrier picks it up

#### Example 3 — large box

(Inside dimensions about 12"x12"x12") For a large shipment of smallpox vaccine and diluent:

- put four 24 oz (600 gm) cold packs on the bottom (See Figure 22)
- use 8 layers of crumpled 2-ply brown paper to separate the cold packs from the vaccine (See Figure 23)



**Figure 18** Put more brown paper on top of the vaccines, and put a cold pack on top of the paper.







**Figure 20** Put crumpled brown paper between the cold packs and the vaccines.



**Figure 21** Put the vaccines close to the cold packs. Add more brown paper, and an additional cold pack on top.

- put the vaccines adjacent to the cold packs in order to maintain the desired internal temperature range
- place a heat monitor close to the vaccines (but away from the cold packs) so the receiver can tell if the temperature stayed within the acceptable range during transit (See Figure 24)
- place a freezing temperature indicator near the outside of the vaccines (See Figure 25)
- use more brown paper on top of the vaccines
- put four "cold" packs on the top (See Figure 26)
- enclose a packing list (See Figure 26)
- seal the box and add labels
- store in the cold unit or in an area with normal ambient temperatures until the commercial carrier picks it up



**Figure 24** Place a heat monitor (outlined in black) close to the vaccines, but away from the cold packs.



**Figure 25** Put in next layer of vaccines. Particularly in winter, put a freezing temperature indicator (outlined in black) next to the side of the box, close to the vaccines which would be damaged by freezing.



**Figure 22** Put 4 cold packs on the bottom of a large box for warm weather shipping of the vaccine.



Figure 26 Add more brown paper, 4 more cold packs on top of the paper, and any inserts you use.



**Figure 23** Put crumpled brown paper between the cold packs and the vaccines.

#### PLACEMENT OF TEMPERATURE MONITORS

Where monitors are placed within the package is important since temperatures vary inside the box. Placing monitors next to the "cold" packs does not give an accurate measure of the temperature of the vaccines that are farther from the "cold" packs. Color-change monitors have adhesive backs and may be attached to vaccine cartons, or walls of the box to prevent them from moving.

A heat monitor (e.g., 3M time-temperature tag), placed at the point of greatest heat exposure (usually near a side, away from cold packs) may have up to, but no more than, four windows blue at the time of unpacking.

A freezing temperature indicator (e.g., ColdMark 32°F monitor), placed with vaccines near cold packs in summer and, also, near a side but away from "cold" packs in winter, should remain clear. (See **Appendices 2A and 2B** for instructions for how to use and read temperature monitors.)

Analog recording monitors are relatively large, and "best judgement" must be used regarding where they should be placed (e.g., in the center or on the outside of the vaccines in a large shipment).

Temperatu	
Fahrenheit	Celsius
- 20	- 29
- 15	- 26
- 10	- 23
- 5	- 21
0	- 18
5	- 15
10	- 12
15	- 9
20	- 7
25	- 4
30	- 1
32	0
34	I
36	2
38	3
40	4
42	6
44	7
46	8
48	9
50	10
52	11
54	12
56	13
58	14
60	16
65	18
70	21
75	24
80	27
85	29
90	32
95	35
100	38
105	41
110	43
115	46
120	49

# 5. APPENDICES

#### APPENDIX I

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#### SMALLPOX VACCINE DO'S FOR DISTRIBUTION FACILITIES

- Do prevent freezing of Smallpox vaccine and its diluent. Keep them at 2°-8°C (36°-46°F).
- Do check the refrigerator unit monitor at least twice daily to be sure the temperature stays between 2° 8°C (36° 46°F).
- Do change the graph paper in the refrigerator monitors as needed (usually weekly). Also check the ink!
- Do ensure the cold facility and refrigerator are locked.
- Do get a security system for the cold facility and train everyone on its use.
- Do have a written plan in case of an emergency power outage.
- Do have a back-up generator and test it regularly.
- Do let the temperature in a new, or newly repaired refrigerator stabilize (~72 hours) before putting vaccines in it.
- Do have standard operating procedures covering the use of every item of equipment and all steps for receipt, storage, and distribution in place; train staff in their use; and continually check for compliance.
- Do have phone numbers of key people available for handling emergencies.

#### APPENDIX 2A — INFORMATION FOR SHIPPERS

#### HOW TO USE TEMPERATURE MONITORS

Time/temperature tags must be kept refrigerated until the moment of use. Pull the tab to activate the monitor. As the temperature inside the package rises to warmer than  $10^{\circ}$ C ( $50^{\circ}$ F), the windows in the monitor turn blue. The more windows that have turned blue, the higher the temperatures reached inside the box or the longer the time warmer than  $10^{\circ}$ C. If no windows are blue, then check whether the monitor was activated. If all five windows are blue, then contact the manufacturer.

The ColdMark Freeze Indicators detects exposure to temperatures under  $0^{\circ}$ C by releasing a red dye marker into a visible bulb. These are usually placed adjacent to cold packs in the summer, and also near a wall in the winter. If the bulb is red, smallpox vaccine may not be usable. Contact the manufacturer.

Analog disposable recording temperature monitors are available which produce linear strip charts over a 4 day period. They may be appropriate for large, expensive shipments. They should be kept refrigerated until used. To start the temperature monitor: fill out the tag with a ball point pen, press hard; peel off the top tag; pull up on the start tab and remove completely. Confirm the unit is ticking. To remove the chart: cut the tamper evident seal; press end and pry up on cassette; remove chart.

All monitors have adhesive backs which can be used to prevent them from moving.



**Figure 27** Time/temperature monitor (far left) has not been activated. The monitor (far right) with all five windows blue, means the vaccine manufacturer should be contacted. (See text for more information.)



**Figure 28** The top indicator is clear, the bottom indicator means the vaccines have been too cold at some point during shipping. (See accompanying text for more information.)



**Figure 29** The box must be broken open and the strip chart removed to determine the temperatures reached during shipping. (See accompanying text.)

#### APPENDIX 2B — INFORMATION FOR RECEIVERS

# READING TEMPERATURE MONITORS IN VACCINE SHIPMENTS

**Time/temperature tags.** As the temperature inside the package rises to warmer than  $10^{\circ}$ C ( $50^{\circ}$ F), the windows in the monitor turn blue. The more windows that have turned blue, the higher the temperatures reached inside the box or the longer the time above  $10^{\circ}$ C.

If no windows are blue, check whether the monitor was activated. If all five windows are blue, contact the manufacturer.

**Color-change monitors, also called a "Freeze Watch" monitor,** detects exposure to temperatures under 0°C by releasing a red dye marker into a visible bulb. These are usually placed adjacent to cold packs in the summer, and on an inside wall in the winter.

Analog disposable recording temperature

**monitors** produce linear strip charts over a 4-day period. They may be appropriate for large, expensive shipments. The monitor should be ticking when you receive it. To remove the temperature chart: cut the tamper evident tape seal; press the end and pry up on the cassette; remove the chart.

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**Figure 30** Time/temperature tags showing all windows are clear, and one to five windows blue.



**Figure 31** A color-change monitor that has not been exposed to temperatures below  $0^{\circ}C$  (32°F) stays clear. When exposed to temperatures below  $0^{\circ}C$  (32°F), the bulb turns red.



**Figure 32** Analog disposable recording temperature monitors. The monitor must be broken open to get the chart strip inside.

SAMPLE LABELS

# REFRIGERATE<br/>UPON ARRIVAL DO NOT<br/>FREEZE DU MERCERATE<br/>DE REEZE DU MERCERATE<br/>FREEZE DU MERCERATE<br/>DE REEZE DU MERCERATE<br/>DE REEZE DE REZEZE DE REZEZE

Various labels that identify your package as valuable cargo.

Ned by LABELMASTER CHICAGO & 60646 (800) 521-5808

#### MATERIALS YOU WILL NEED FOR YOUR PACKING AREA

- Insulated boxes: small, medium and large
- Vaccine: directly from the cold room
- Fillers: crumpled brown paper, styrofoam "peanuts", or bubble wrap
- Cool packs: either permanently sealed or plastic bottles with leak-proof caps
- Temperature monitors: e.g., analog disposal recording monitors, color-change monitors, time/temperature tags
- Insert: packing list

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- Sealers: tape or plastic straps
- Labels: content, value, caution

Record-keeping sheets and log books or computer terminals need to be provided in the packing area to record any deviations from standard procedures, including storage temperature units going outside established temperature ranges. Records of all such deviations should be filed with supervisory/managerial staff for at least three years and responses to each situation recorded.

#### WHERE CDC OBTAINED MATERIALS FOR TESTING PACKING METHODS

#### Cardboard-covered insulated boxes

Molded polystyrene, Polyfoam Packers Corp., Wheeling, Illinois Isocyanurate, True pack Ltd, Wilmington, Delaware Molded polyurethane, Normco Inc, Beltsville, Maryland

#### Cold packs

Chemical gel packs, U-TEC, manufactured by Polyfoam Packers Corp., Wheeling, Illinois.

#### Plastic Bottles

WHO-approved, capped bottles, Electrolux, Vianden, Luxembourg

#### **Monitors**

Analog temperature recorders, Marathon Temperature Recorder Co., Modesto, California Color-change monitors "ColdMark Freeze indicator", IntroTech Inc, St. Paul, Minnesota "MonitorMark Time/Temperature Tag, model 10-1" indicators, 3M Specialty Packaging Department, St. Paul, Minnesota

#### Fillers and Sealers

Brown paper, styrofoam peanuts, bubble wrap, tape or plastic straps - office or packaging suppliers.

Samples of any materials received should be tested to verify they meet specifications and function as required under local circumstances.

#### **DISCLAIMER**

The use of proprietary names and description of specific manufacturers' products does not imply endorsement by the Centers for Disease Control and Prevention, or the U.S. Department of Health and Human Services.

#### SMALLPOX VACCINE ORDERING AND SHIPPING PROCESS

- The order is received in the shipping department. Inventory controls identify which smallpox vaccines will be selected.
- Smallpox vaccines are pulled from systematically organized smallpox vaccine stocks.
- Vaccines are set on a work counter and checked carefully against the order need.
- The appropriate sized box is selected, based on the quantity of vaccine being shipped.
- Smallpox vaccine packed with enough cold packs to keep the appropriate internal temperatures throughout the shipping process.
- Temperature monitors are placed in appropriate locations in the package to detect potentially harmful temperature exposures during shipping.
- All remaining empty space in the box is filled with some kind of filler material.
- A packing list is enclosed.

- The box is sealed with tape or plastic straps to insure that it remains tightly closed.
- A shipping label, coded for the size of the box being shipped, is affixed, so that if the box is misplaced, it will be easier to locate.
- Labels are applied so that they are clearly visible on the outside of the box, to let everyone know that the contents include vaccines which must be handled properly.
- Once the box is packed, sealed, and labeled, it is stored until it is picked up by the commercial carrier or designated clinic personnel. Other packages may be similarly stored or placed in a refrigerated area, if space is available, or at ambient temperature, depending on when the carrier picks up packages.

#### CHART OF COLD PACK NEEDS FOR DIFFERENT CLIMATES

° [] F*	Outside Temperature	No. faces covered with cold packs	Temperature of cold/cool packs	Comment*
┠╎╉─	– 110°F			
		2§	-5°C (25°F)	up to 48 hrs delivery with 10hr at 110°F
	>75°F			
	<b>-</b> 75°F			
		<b>2</b> §	-5°C (25°F)	48 hrs delivery
		4	+5°C (45°F)	up to 24 hrs
	<b>-</b> 32°F <32°F			
	021	4 – 6 <sup>¶</sup>	+5°C (50°F)	about 24 hours exposure to mix outdoors & heate areas
	0°F or colder 24-48hrs	6¶	+20°C (68°F)	prolonged,
				continuous exposu to 0°F (-20°C)
	* Applies when	high quality insulated	hoxes with walls of I	." to 23" expanded

<sup>§</sup> 3 for the medium box tested by CDC.

 $\ensuremath{^{\mathrm{T}}}$  Essentially the entire surface area is covered with "cool" packs