Standard Operating Procedure

Responding to emergencies in fixed storage locations

Approvals	Name	Date	Signature
Authorized by:	Ministry of Health		
Reviewed by:	Rwanda, UNICEF CO	May 2016	
Revised by:	Vaccine Preventable Disease Program	October 2015	
Original author:	WHO		

Version history

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1	07 Oct 2011	Original	
2	16 May 2016	Edited and adopted to Rwanda context	
3			
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Standard Operating Procedure

Responding to emergencies in fixed storage locations

1. Policy and objectives

1.1 Policy

All responsible personnel should know when and how to respond in the event of cold chain equipment breakdown or a major power supply failure. All staff may simply be required to report to the in charge of maintenance (At central or District depending to the level) and inform immediately to his/her supervisor (cold chain senior officer at central level or EPI supervisor at DH level).

During out of normal working hours (Weekends, nights, holidays) the available supporting staff including security guards should call the in charge of maintenance and/or cold chain senior officer. All staff in vaccine supply chain management desk should know and understand the emergency response plans and should be able to implement effectively if the need arises.

1.2 Objectives

This SOP describes the actions that should be taken in response to some commonly occurring emergencies at Central Vaccine Store and District stores where large quantities of vaccine are stored. The SOP also covers emergency responses in lowest delivery level stores (Health facilities).

Elements of an emergency response plan for a district hospital and health centre vaccine stores.
Ensure that all personnel know how to follow safe storage rules in an emergency.
• *Freeze-sensitive vaccines:* Maintain vaccines at +2°C to +8°C – see Annex 1.
• *OPV and freeze-dried vaccines*: Maintain vaccines at +2°C to +8°C or use available ice to keep freeze dried vaccines and OPV – see Annex 1.
• *Diluents***:** Store at room temperature, unless packed with the vaccine[1].
Identify a range of emergency response options
• Move vaccines to RBC, MPDD (CAMERWA) public service cold store: From district hospital or health centre to nearby cold chains located in district or health centre or vice versa. • At service delivery level (Health facility) move vaccine to the nearest health facility with adequate storage capacity. Each health facility should prepare and know the health facility that vaccines will be moved when emergency exists as a contingency plan.

[1] At service delivery level, diluent should always be stored at +2°C to +8°C, even during an emergency.

• Borrow or hire a refrigerated vehicle,
• Move vaccine to a private sector cold store or refrigerator and ensure continous cold chain temperature monitoring devices are inplace, and working.
• Closely monitor private storage cold room temperature(if rented) and keep until repairs are carried out.
Prepare and maintain at least two emergency response plans based upon these options.
• Whatever plans you choose, make sure they are discussed with all parties involved and agreed on, beforehand with program staff.
• Confirm the plan in writing. Keep a copy in the vaccine store. Make sure responsible personnel know where it is.
• Check alternative stores to ensure that they are in good condition, have adequate space and are capable of maintaining vaccine at the correct temperature. There is no point moving stock to another cold room only to find that all your freeze-sensitive vaccine is frozen and destroyed.
• Do not wait until an emergency occurs. Rehearse[2] the plans *before* they are needed.
• Prepare a list of emergency contact names, addresses and telephone numbers and post a copy of the list in the vaccine store. Keep the list up to date.
• Make sure that emergency contacts can be made both inside and outside normal working hours.

Source: WHO/IVB/04.16-20. *EVSM Model Quality Plan*

2. Responsibility

All personnel who have responsibility for looking after vaccines in fixed storage locations, including security guards who provide out-of-hours cover.

3. Associated materials and equipment

4. Telephone and airtime to be availed for the supporting staff (guards) Procedure

4.1 Contact details

Every vaccine store and health facility must post emergency contact details on a notice board and in a place where it can be read outside of working hours. The emergency details must include:

[2] Vaccine should not be physically moved during rehearsals, but all key procedures should be simulated.

a. Names of the responsible personnel member(s), with office and personal telephone number(s).

b. Names of both maintenance engineers with office and personal telephone number(s).

4.2 Emergency responses at Central vaccine store and District vaccine stores

This section describes the immediate actions to take in the case of foreseeable emergencies. In the case of an unforeseen event, all responsible personnel must be contacted and they must meet as soon as possible to decide on the specific action to be taken.

*4.2.1 **Temperature alarm activated***

Initial response outside working hours:

a. Responsibility: **Security guards to contact vaccine stock management officer/ senior cold chain officer and Maintenance engineer.** The emergency contact numbers until one person answers and agrees to respond.

b. Wait until the responsible person arrives to investigate and provide assistance as requested.

Follow-up response:

Responsibility: **Maintenance engineer, senior cold chain officer, vaccine management officer.**

a. *Locate the source:* Identify the equipment which is generating the alarm.

b. *Door or lid open:* Check to see if the alarm is caused by an open door or open lid. If it is, close the door or lid and wait to see if the temperature returns to normal.

c. *Check the power supply:* Check whether the power supply to the equipment has been disconnected or switched off. If it has, reconnect the equipment and wait to see whether the temperature returns to normal.

d. *Cold room or freezer room not cooling:* Switch over to the standby unit. Call the maintenance engineer or responsible RBC/ MTI staff.

e. *Freezer room not working:* Move the vaccine to another freezer. If there is insufficient space available, move the vaccine to a cold room or to a vaccine refrigerator.

f. Record the new location of the vaccine in the stock control system.

g. *Cold room or refrigerator not working:* Move vaccine to another cold room or to another vaccine refrigerator. Call the maintenance engineer or responsible staff at RBC/MTI.

h. Record the new location of the vaccine in the stock control system.

4.2.2 Mains power failure – generator not starting

Initial response outside working hours:

Responsibility: **Security guards to contact Senior cold chain officer/ VPDP director, vaccine stock management officer and RBC/MTI maintenance engineer.**

If the mains power supply returns within one hour, report the generator failure to the responsible person on the next working day so that the maintenance engineer or Cold chain senior officer can be called to fix it.

a. If the mains power supply does not return within one hour, call the responsible members of personnel, maintenance engineer or Cold chain senior officer.

b. Wait until the responsible person arrives to investigate and provide assistance as requested.

Follow-up response:

Responsibility: **Maintenance engineer, Senior Cold chain officer, vaccine supply chain, Vaccine stock management officer**

a. *Minor defect:* Rectify the defect within 24 hours and test the generator.

b. *Major defect:* Notify the electricity supply company that the standby generator is not working and that power cuts lasting more than two hours in 24 hours will place the vaccine at risk. Rectify the defect within seven days.

c. *Major breakdown requiring generator replacement:* Rent a mobile generator from private company and make the necessary temporary connections to the control panel.

d. Order a permanent replacement generator and install when it arrives.

Note: At least one standby generator should be available.

4.2.3 Fire

Initial response outside working hours

Responsibility: **Security guards to contact fire brigade/local police authority, VPDP director, senior cold chain officer, vaccine stock management officer, supply chain officer.**

DO NOT place yourself at risk.

a. If the fire is small, try to extinguish it using the nearest available fire extinguisher.

b. Immediately contact the fire service.

Police (fire brigade) contact telephone number: +250XXXXXXXX

OTHERWISE:

c. Leave the building.

Table: Emergency response plan for district hospital and health centre cold chains.

	Type of Equipment	Possible scenario	Responsibility	Responsible person	Contact address
1	Cold room	Power failure for less than 1 hour	• Closely monitor/observe temperature of cold room.	• Vaccine stock management officer, • senior cold chain officer	+250788XXXXXX
		Power failure for more than 1hour	• Report to supervisor and prepare for worst case scenario, • Report to RBC/MTI cold chain maintenance engineer,	• Vaccine stock management officer, • Senior cold chain officer	+250788XXXXXX
		Equipment break down	• Report to RBC/MTI cold chain maintenance engineer, • Move vaccines to next cold chain according to emergency response plan	• Senior cold chain officer • VPDP director	+250788XXXXXX
2	Refrigerator	Power failure for less than 4hours	• Closely monitor/observe temperature of refrigerator.	• Vaccinator, EPI supervisor • Vaccine stock management officer,	+250788XXXXXX
		Power failure for more than 4 to 6 hours	• Shift vaccines to ice lined refrigerator, • Shift vaccines to cold box with adequate frozen icepack • Shift vaccines to nearest health facility with frozen/conditioned ice packs, • Contact district EPI supervisor and District biomedical technician for further maintenance	• Vaccinator • vaccine stock management officer, • EPI supervisor	+250788XXXXXX
		Equipment break down	• Contact district EPI supervisor and District biomedical technician for further maintenance • Report to RBC/MTI for further maintenance	• Vaccine stock management officer, • EPI supervisor • Hospital director	+250788XXXXXX
4	Refrigerator at HC	Power failure for less than 4hours	• Closely monitor/observe temperature of refrigerator.	• Vaccinator, EPI supervisor • Vaccine stock management officer,	+250788XXXXXX
		Power failure for more than 4 to 6 hours	• Shift vaccines to ice lined refrigerator, • Shift vaccines to cold box with adequate frozen icepack • Shift vaccines to nearest health facility with frozen/conditioned ice packs, • Contact district EPI supervisor and District biomedical technician for further maintenance	• Vaccinator • vaccine stock management officer, • EPI supervisor	+250788XXXXXX
		Equipment break down	• Contact district EPI supervisor and District biomedical technician for further maintenance • Report to RBC/MTI for further maintenance	• Vaccine stock management officer, • EPI supervisor • Hospital director	+250788XXXXXX
5	Generator	Generator does not start	• Check fuel level and battery,	• Generator operator, Vaccine stock management officer	+250788XXXXXX
			• Report to RBC/MTI engineer for further maintenance	•	+250788XXXXXX
		Generator major break down	• Maintenance of generator and electrical switch board,	• RBC/MTI engineer	+250788XXXXXX
5	Voltage stabilizer	No output from voltage stabilizer	• Disconnect from mains and directly plugin the equipment	• Vaccine stock management officer	+250788XXXXXX
		• Maintain and repair stabilizer	• RBC/MTI engineer	+250788XXXXXX	• Maintain and repair stabilizer

4.2.4 ***Major emergency, including action following a fire***

Responsibility: VPDP director, maintenance engineer, cold chain senior officer, Vaccine stock management officer, vaccine supply chain officer.

Call an emergency meeting to agree the action plan.

a. Enter the store only if it is safe to do so. Inspect the stock and establish which vaccines and other supplies are physically undamaged. Check VVM status. Safely dispose of any vaccines that have reached the discard point.

b. Move the vaccines and other supplies as quickly as possible to a safe alternative location.

c. Conduct a physical count of the salvaged vaccine and other supplies.

Note: Prepare an emergency response plan to deal with this situation. Two possible options include moving vaccine to another store or storing vaccine temporarily in refrigerated vehicles.

5. Related documents and SOPs

- EVM-SOP-E2-03: *Correct storage temperatures for vaccines and diluents*
- EVM-SOP-E5-02: *Looking after cold rooms and freezer rooms*
- EVM-SOP-E5-03: *Looking after vaccine refrigerators and freezers*
- EVM-SOP-E5-04: *Looking after standby generators*
- EVM-SOP-E5-05: *Looking after voltage regulators*
- EVM-SOP-E6-04: *Safe disposal of expired or damaged vaccine and diluents*
- EVM-SOP-E7-04: *Conditioning frozen icepacks*
- EVM-SOP-E8-02: *Using Vaccine Vial Monitors*

Annex 1 – WHO recommended storage temperatures

<table>
<tr><th rowspan="3">Vaccine</th><th rowspan="2">Primary</th><th colspan="2">Sub-national</th><th rowspan="2">Health Facility</th><th rowspan="2">Health Post</th></tr>
<tr><th>Province</th><th>District</th></tr>
<tr><td colspan="3">Maximum storage period</td><td colspan="2">Maximum storage period</td></tr>
<tr><td>6-12 months</td><td>3 months</td><td>1 month</td><td>1 month</td><td>According to session plan</td></tr>
<tr><td>OPV</td><td colspan="2">Store at -15°C to -25°C
OPV is the only vaccine that can safely be frozen and unfrozen repeatedly</td><td colspan="3">Store at +2°C to +8°C</td></tr>
<tr><td>BCG
Hib lyophilized
JE
Measles
Meningitis
MMR
MR
Yellow Fever</td><td colspan="3">Store these lyophilized vaccines at +2°C to +8°C.
Under exceptional circumstances they can be temporarily stored at -15°C to -25°C (e.g. if there is a temporary shortage of storage space. Never freeze diluent.</td><td colspan="2" rowspan="16">Store at +2°C to +8°C
DO NOT FREEZE</td></tr>
<tr><td>Cholera
DT/TT/Td
DTP
DTP-HepB
DTP-HepB+Hib lyo
DTP-HepB-Hib liquid
DTP-Hib
Hepatitis B
Hib liquid
HPV
Influenza
IPV
Pneumoccocal
Rabies
Rotavirus</td><td colspan="3">In an emergency, all these vaccines can be stored at +2°C to +8°C</td></tr>
<tr><td colspan="6">Diluent: If diluent is included in the vaccine packaging, store it between +2°C and +8°C. However, if diluent is supplied separately, it can be stored outside the cold chain but must be cooled before use, preferably for a day or for a period of time sufficient to ensure that the vaccine and diluent are both at temperatures between +2°C and +8°C when they are reconstituted. Never freeze diluent.
Note that diluent/adjuvant for some pandemic influenza vaccines must be stored in the cold chain.</td></tr>
</table>

Source: WHO/IVB/08.01: *Training for mid-level managers: Module 1 - Cold chain, vaccines and safe-injection equipment management.* Updated in April 2011 by WHO/IVB/QSS to include additional vaccines.

	Standard Operating Procedure **Installing and looking after vaccine refrigerators and freezers**		
Approvals	**Name**	**Date**	**Signature**
Authorized by:	Ministry of Health		
Reviewed by:	Rwanda, UNICEF CO	May 2016	
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Table of content

Distribution

Distribute this SOP to the following:

Facility type	Position(s)
DHL	
HC	

Standard Operating Procedure

Installing and looking after vaccine refrigerators and freezers

5. Policy and objectives

5.1 Policy

Responsible personnel should know how to operate the refrigeration, temperature monitoring and alarm equipment, know when routine maintenance is required, and know how to recognize common faults. They should also understand the principles of planned preventive maintenance and routine equipment replacement and their importance for the maintenance of a reliable cold chain.

5.2 Objectives

This SOP tells you how to install new vaccine refrigerators and freezers and covers routine non-mechanical maintenance and responses to emergency maintenance.

This equipment is a critical component of the national vaccination programme. Any mechanical failure which places the vaccine at risk is unacceptable and the preventive maintenance regime described in this SOP must be strictly followed.

If a mechanical failure does occur, the problem must be rectified within a maximum target periods stated in this SOP by a trained maintenance technician. It is essential that a sufficient stock of spare parts is maintained to ensure that these targets can be met.

6. Responsibility

Responsibility for routine non-mechanical maintenance, simple troubleshooting and initial emergency responses rests with in charge of maintenance at central vaccine store and district level, EPI Supervisors and users at health facility level.

Responsibility for mechanical repairs rests with senior cold chain officer, district biomedical technicians.

7. Associated materials and equipment

Cleaning materials, tools and spare parts.

Attached as annex,

8. Procedure

The procedures set out below do not cover temperature monitoring tasks. For these tasks, refer to EVM-SOP-E2-01: *Monitoring vaccine storage temperatures at fixed storage locations.*

8.1 Training

Responsibility: Senior cold chain technician and cold chain maintenance engineer of RBC/MTI.

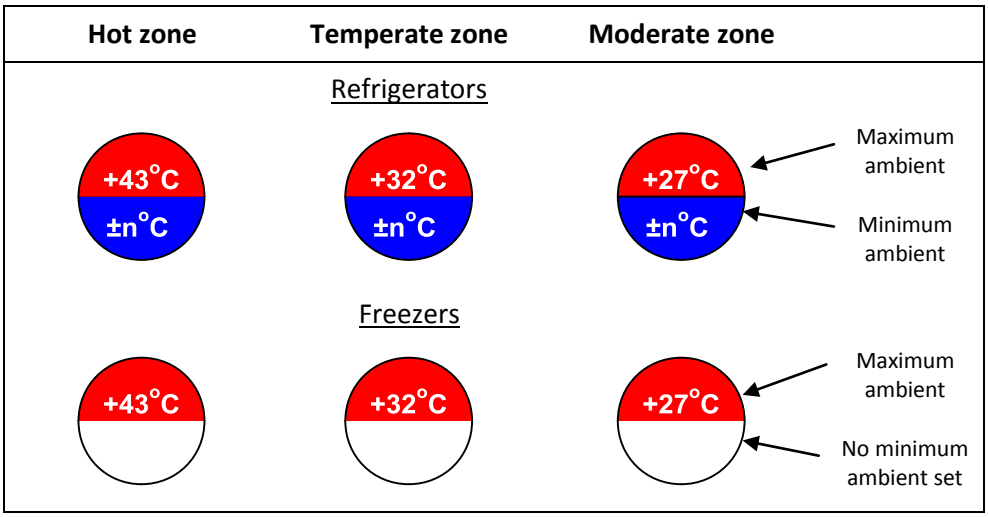
All personnel who are responsible for looking after vaccine refrigerators and freezers should receive appropriate hands-on training to ensure that they are capable of carrying out all of the tasks set out in this SOP.

8.2 General installation instructions for refrigerators and freezers

It is essential that refrigerators and freezers are installed correctly. Follow the procedures set out below whenever new equipment is installed and whenever existing equipment is moved to a new location.

Responsibility: District biomedical technician, vaccination programme focal point (District level) and vaccination programme focal point at Health Center.

a. *Temperature zones:* WHO pre-qualified equipment is supplied with a temperature zone sticker of the type shown below. Before installation, make sure that the equipment is correctly rated for the maximum and minimum ambient room temperatures at the installation site. If the ambient room temperature is too high or, for refrigerators, is too low, the equipment will not maintain the correct vaccine storage temperature.



b. *Unpacking:*

- Check the packing case. If there is damage, notify the supplier before unpacking. Otherwise, unpack the equipment carefully and remove all packing materials.

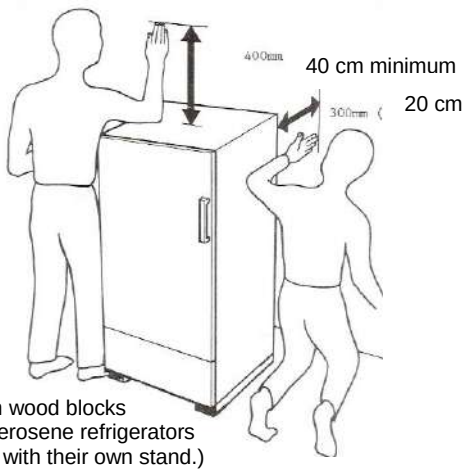
- Check the equipment. If there is damage, notify the supplier.

c. *Manual:* Read the manufacturer's installation and operating instructions and follow them exactly. When you have finished the installation and commissioning, file the instruction manual in a safe place. Alternatively, put the manual into a heavy duty plastic wallet and fix the wallet with double-sided tape to the side of the refrigerator/freezer.

d. *Choose a suitable location.* Make sure the room is well-ventilated and the floor is level, dry and clean. Choose the coolest location available; DO NOT place equipment in direct sunlight. Do no install on places where refrigerator is going to be exposed to direct sun light. For mains electric units, choose a location close to an electrical socket or arrange power source inside the room.

Position the equipment correctly: Position the equipment so that it is easily accessible and is spaced away from adjacent walls furniture and other equipment. Make sure you can open the lid or door completely. Comply with the minimum clearances specified in the equipment manual. If the manual is not available, leave 30 cm clearance behind the unit, 30 cm clearance on both sides of the unit and at least 40 cm above the unit.

Level the equipment. Some manufacturers provide plumb bob to check that the unit is level. Otherwise, place a spirit level or saucer full of water on top of the unit to ensure that it is level. Adjust the feet or use packing pieces as necessary. Unless the equipment has wheels or a stand, place the feet of the unit on wooden blocks about 5 cm thick x 10cm wide as shown below. This ensures that the equipment is kept clear of the floor so that it is not damaged by floor washing. It also allows the floor to be cleaned underneath the equipment.



5 x 10 cm wood blocks
(except kerosene refrigerators
and units with their own stand.)

e. ***Allow refrigerant to settle:*** If the equipment has just been delivered, or has been stored on its side (for Kerosene refrigerator only), leave it in its final position for 06 hours before turning it on to allow the refrigerant to settle. For compression type refrigerator storage on its side will consequence a major break down. NEVER STORE REFRIGERATOR ON ITS SIDE. Check the manufacturer's installation instructions.

8.2.1 ***Installation of mains electric refrigerators and freezers***

Responsibility: District biomedical technician, vaccination programme focal point (District level) and vaccination programme focal point at Health Center.

a. *Ice-lined refrigerators*. If they are empty, fill the ice-lining container(s) with clean tap water and install the vaccine baskets exactly as shown in the instruction manual[3].

b. *Connect the equipment to a voltage regulator.* Plug the equipment into a voltage regulator. DO NOT use adaptors (extension cables) to connect more than one piece of equipment to a single regulator (check for capacity of extension wire). If the power lead is too long DO NOT coil it up[4]. Lay the cable out in long loops on the floor behind

[3] A few manufacturers provide a container of ice-lining fluid with the product. In such cases, use the fluid supplied.

[4] If you do this, the coil will heat up and may melt and cause a fire.

the unit, or ask a qualified electrician to shorten the lead. Only connect one regulator to each wall socket. NEVER use extension leads or adaptors.

c. *Ice-lined refrigerators with adjustable thermostats:* Ice-lined refrigerators with adjustable thermostats[5] may freeze or heat up vaccines if not correctly set up. If there is an adjustable thermostat set it to '2' or 'MEDIUM' and put adhesive tape over the thermostat dial so that it does not get changed. After 5 to 6 hours or when the thermostat switches off the compressor stops running, at this time check temperature reading. If the temperature is less than +2°C at any time, reduce the thermostat to '1' or 'MINIMUM' setting and re-tape the thermostat or if it's above 8°C increase the setting from two to three and follow until compressor rests when thermostat switches it off. When thermostat switches off again check temperature, and continue adjustment until temperature is 5°C and thermostat switches off running compressor. See **Annex 1**.

Once thermostat start controlling at about 5°C allow equipment to run and leave for at least 24 hours. The temperature should stabilize within the correct range (+2°C to +8°C most preferable at 5°C). DO NOT adjust the thermostat again, even if the power goes off, or if the temperature rises above +8°C when door is opened to load and unload vaccines.

d. *Conventional refrigerators and freezers:* Turn the equipment on[6]. Leave the temperature to stabilize for at least 24 hours. Check that the temperature is within the correct range (+2°C to +8°C most preferable at 5°C for vaccine refrigerators and -15°C or below for icepack freezers). If there is an adjustable thermostat, change the setting as necessary.

DO NOT put vaccine into the equipment until you are sure that the temperature is absolutely correct.

8.2.2 Installing kerosene operated refrigerators and freezers

Responsibility: **District biomedical technician, District EPI supervisor, vaccinator at health facility**

a. *Keep clear of draughts:* Do not place the unit close to doors or windows or between doors and windows where there is draught.

b. *Access to kerosene tank:* Make sure there is enough space all round refrigerator to access the kerosene tank. If the tank is at the back, you may have to pull the unit forward on its wheels to do this

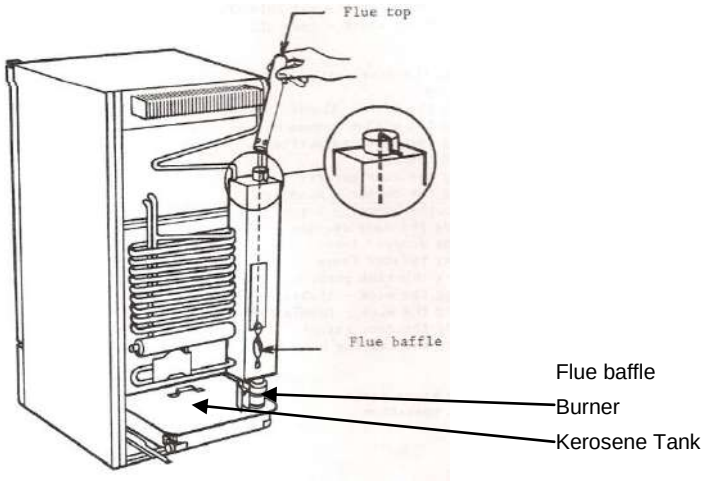
c. *Burner and flue components:* Make sure that all burner and flue components are correctly installed.

Flue top

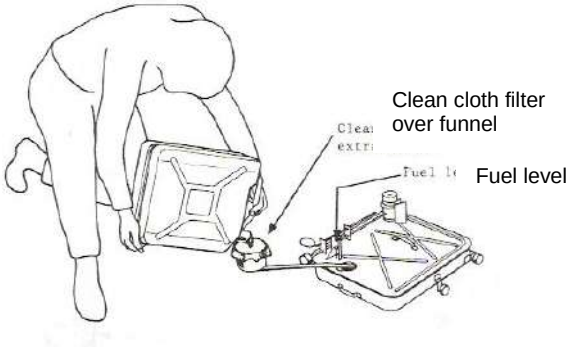
[5] This task has become unnecessary with the latest PQS pre-qualified mains and solar electric compression refrigerators and freezers. Since 2009, these units have been fitted with non-adjustable thermostats,

[6] If the equipment has just been delivered, you may have to leave it for a period of time to allow the refrigerant to settle. Check the manufacturer's installation instructions.

Kerosene operated refrigerator



d. *Kerosene units:* Fill the tank with kerosene and allow the wick to soak for at least three hours before lighting. Unless the kerosene is guaranteed to be of high quality, always filter the fuel before putting it in the tank.



e. Dual fuel units: If the unit is supplied with an electrical connection, NEVER operate the equipment using kerosene when the electrical supply is connected. Make sure that electrical supply is unplugged from the wall socket before lighting the burner.

f. *Check equipment operation (Kerosene): L*ight the burner, check that the flame colour is as described in the manual (blue for Aladin burner and yellow for cosmos burner). Leave the temperature to stabilize for at least 24 hours. Check that the temperature is within the correct range (+2°C to +8°C for refrigerator cabinet and -5°C or below for freezer cabinet). Adjust the burner setting as necessary. DO NOT put vaccine into the equipment until you are satisfied that the temperature is correct and stable at least for 24 hours.

g. *Check equipment operation (Electricity):* If you have a dual fuel unit and an effective electrical supply, make sure you also test the unit using electricity. You may need to change from one fuel source to another and it is essential to know that unit operates correctly on both.

- Extinguish the burner and connect the unit to the electricity supply.
- Use a voltage regulator of a type suitable for absorption refrigerators.

- Check that the temperature is within the correct range (+2°C to +8°C for vaccine refrigerator compartments and -5°C or below for freezer compartments). Adjust the thermostat setting as necessary.
- DO NOT put vaccine into the equipment until you are sure that the temperature is correct and stable.

8.2.3 ***Installation of solar refrigerators and freezers***

Solar refrigerators and solar power systems MUST be installed and commissioned by a trained solar technician. Detailed installation and commissioning checklists are attached with equipment and general guideline is available in WHO/PQS/PV01-VP2.2: *Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.*

Warning: Never connect other equipment, such as lights, radios or cell phone chargers, to the solar power system. The system is designed to operate the refrigerator/freezer only[7].

4.*2.4* ***Installation of solar direct drive refrigerators and freezers***

Solar direct drive refrigerators and freezers MUST be installed and commissioned by a trained solar technician. Detailed pre installation site assessment, installation, commissioning and maintenance checklists of UNICEF's SDD Support package is attached in Annex.

8.3 Routine use and maintenance for all refrigerators and freezers

8.3.1 Routine use

Responsibility: EPI supervisor, User at health facility,

DO NOT use vaccine refrigerator or freezer to store food and drink. Personal use of a vaccine refrigerator is absolutely prohibited.

a. DO NOT place vials or boxes of vaccine in contact with the walls of the refrigerator or freezer. Leave spaces between boxes to allow for air circulation.

b. AVOID over-stocking a refrigerator or freezer – this will prevent it from cooling properly.

8.3.2 Daily tasks

Responsibility: District Level, EPI supervisor and vaccinator

c. Check temperatures as described in EVM-SOP-E2-01: *Monitoring vaccine storage temperatures at fixed storage locations.*

d. Only adjust the thermostat or flame control setting if the temperature of the vaccine storage compartment is outside the correct temperature range. The correct temperature ranges are:

- ALL vaccine refrigerators: +2°C to +8°C;
- Main electric compression cycle freezers: -15°C to -25°C;

[7]Unless the facility has a centralised solar power system. In which case, the vaccine refrigerator or freezer must be on a priority demand circuit.

- Gas, kerosene or electric absorption cycle freezers: -5°C or below.

NOTE: Refrigerators pre-qualified by WHO since 2009 have non-adjustable thermostats fixed at the correct temperature. If the temperature in one of these products is not in the correct range, contact your supervisor.

AVOID frequent adjustments. If you do need to adjust the thermostat or flame setting, check carefully over the next few days that the new setting is correct and temperature is between +2°C to+8°C.

DO NOT adjust the thermostat to a higher setting when a new vaccine delivery arrives. This could freeze the vaccines.

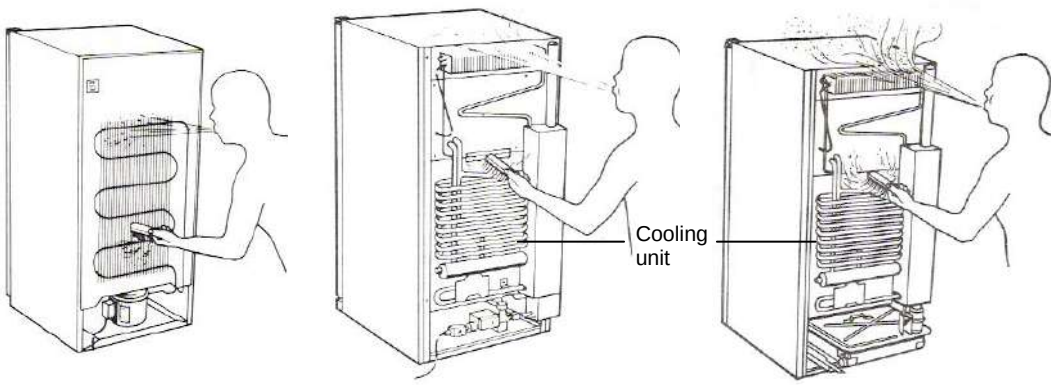
DO NOT adjust the adjustable thermostat on an ice-lined refrigerator once the thermostat has been correctly set and taped in position (see 4.2.1d).

DO NOT adjust the thermostat on any type of appliance when the power is restored after a power cut.

8.3.3 Monthly tasks

Responsibility: Maintenance technician at District Level

a. Check that the condenser and cooling unit on the back of the unit is clean. Remove any dirt or dust with a soft brush. The equipment will not work correctly (or efficiency is compromised) if these components are clogged with dust.



Mains electric compression (including ice-lined and solar units) **Gas absorption** **Kerosene absorption**

b. Clean the outside of the unit with a damp cloth.

c. Clean the lid or door gasket with soap and water.

d. Defrost the unit as described in the box below**.** You should defrost the unit once a month, or whenever the ice on the inside lining is thicker than 5mm. Check for ice formation on the inside lining. If the unit needs defrosting more than once a month, check whether the door or lid gasket is damaged and check that the door or lid is closing correctly. If there is a problem, ask the maintenance technician to carry out repairs.

Defrosting a refrigerator or freezer:

Step 1: Transfer the existing contents to a safe place: Prepare cold box lined up with conditioned icepacks for freeze sensitive vaccines, and separate cold box with frozen ice packs for heat sensitive vaccines or if there is only one cold box prepare conditioned ice pack to keep all vaccines

together,
Remove the most heat-sensitive vaccines (<list heat-sensitive vaccines in schedule>). EITHER transfer them to a cold box lined with frozen ice-packs, OR transfer these vaccines to another vaccine refrigerator or freezer.

Remove the freeze-sensitive vaccines (<list freeze-sensitive vaccines in schedule>) and diluents. EITHER transfer them to a cold box lined with conditioned ice-packs, OR Transfer these vaccines to another vaccine refrigerator.

Transfer any frozen ice packs to a cold box or to another freezer.

Transfer any cool water packs or water bottles or to a cold box or to another refrigerator.

Step 2: Turn off the power supply to the refrigerator or freezer, or extinguish the burner.

Step 3: Leave the lid or door open and wait for the ice to melt. Do not try to remove the ice with a knife or other sharp object. Doing this can permanently damage the lining.

Step 4: Clean and dry the inside of the refrigerator.

Step 5: Turn the refrigerator on again, or re-light the burner.

Step 6: Wait until temperature reaches between+2^{o}C to +8^{o}C

Step 7: Return vaccines to their original places as per temperature sensitivity.

REFRIGERATORS: When the temperature in the refrigerator compartment is between +2°C to +8°C return the vaccines, diluents, and/or cool water packs or water bottles.

FREEZERS: When the temperature falls to -5°C or lower, return the vaccines, diluents, and/or ice-packs.

8.3.4 Annual tasks

Responsibility: Maintenance technician at District Level

a. Check the door or lid gasket, replace if it is defective.

b. Check the outside of the cabinet for damaged paint work or rust. If there are signs of damage, clean the affected surfaces and remove all rust. Treat the bare metal with a rust inhibitor, apply a coat of metal primer and repaint the damaged surface with enamel paint.

c. Check the inside of the cabinet for signs of damage, including corrosion to shelves or the wire baskets in ice-lined refrigerators. Carry out repair work as necessary.

d. Review your stock of spare parts and consumables, such as wicks, lamp glasses, battery electrolyte, etc. Restock all items that are out of stock or in short supply.

8.4 Specific maintenance for kerosene refrigerators and freezers

8.4.1 Daily tasks

Responsibility: Vaccinator at health facility/xxx)

Fill the tank: Fill the tank with clean kerosene. See 4.1.2 d.

a. *Burner flame:* Check that the flame height and colour is correct for the type of burner fitted. If the flame smokes, turn it down a bit. If it still smokes, clean or trim the wick, burner, flue and baffle as shown in the instruction manual. ALWAYS clean the flue if the flame has been smoking.

b. *Note:* ALWAYS fill the tank before it is completely empty. ALWAYS keep enough spare kerosene to ensure you never run out. NEVER use any other fuel (e.g. diesel or gasoline)

8.4.2 Weekly tasks

Responsibility: User level at health facility

a. *Clean the burner, flue and baffle:* Clean the burner, flue and baffle as shown in the instruction manual.

b. *Check the fuel supply:* Check that you have enough kerosene for at least another week. If not, replenish the supply immediately.

c. *Check the wick: Check* the wick that it reaches bottom of fuel tank to absorb adequate kerosene to light. If necessary and wick top is dried trim the wick as shown in the instruction manual. Use a wick trimmer supplied.

8.4.3 Monthly tasks

Responsibility: Maintenance technician at District Level

a. *Clean the tank:* Check the fuel tank to see if there is sediment at the bottom. If there is, blow out the burner and remove the tank. Remove the burner from the tank. Empty out the dirty kerosene. Flush the tank with a little clean kerosene. Wipe the outside of the tank with a clean cloth dipped in kerosene. Replace the burner and refill the tank.

b. *Replace the wick:* Replace the wick when you cannot turn it up any more to increase flame size and when necessary to trim it. Use the correct type of wick and follow the instruction manual. ALWAYS keep two spare wicks in a safe place.

8.5 Specific maintenance for solar refrigerators and freezers

8.5.1 Daily tasks

Responsibility: User level at health facility

a. Record temperature twice daily in the log book.

b. Record if there is any alarm indicator gets visible.

c. *Check refrigerator/freezer control panel status:* Check the status of the control panel display. Take appropriate action as described in the instruction manual if status is not normal.

d. *Check battery charge status (battery systems only):* Check the indicator lights on charge regulator. DO NOT freeze water packs if the low battery warning light is on. Move vaccine to a safe location if the load-disconnect warning light or alarm is activated.

8.5.2 Monthly or periodic tasks

Responsibility: (user level)

a. *Check battery electrolyte (flooded battery systems only):* Check electrolyte levels and top up at the intervals given in the user manual or when only required. Use distilled water ONLY. You MUST wear hand, eye and clothing protection when carrying out this task and follow the manufacturer's recommended safety precautions.

b. *Clean dust from the solar array:* Clean the solar array monthly to remove accumulated dust, *leaves and any material* which will shade solar cells and reduce performance. The frequency at which this needs to be done will vary. **In very dusty areas, clean the array twice in a month, if not once in a month is enough. In a rainy season the frequency of cleaning will be lower.**

- DO NOT attempt to carry out this task unless you have the correct access and safety equipment and have received training in safe working at height. Make sure you have somebody to help you and to hold the ladder.
- NEVER stand on corrugated roof sheets – use a properly designed roof ladder to climb up.
- Clean the array early in the morning or evening when the sun is weak.
- Use a soft cloth wetted with water. Wipe gently, starting at the top and working downwards.
- Do not lean or stand on the array panels because you may damage them.
- Report any damage to wiring or hardware to your supervisor.

8.5.3 Annual tasks

Responsibility: Maintenance technician at District Level

a. *Check array shading:* Make sure that the solar panels are not shaded by trees, plants, new buildings or overhead cables between 9.00 am or 3.00 pm. If there is shading from vegetation, arrange for the vegetation to be cut back or discuss with facility supervisor for further actions. If there is shading from newly constructed buildings or new overhead cables, contact supervisor, the solar array (cold chain) may have to be moved to other location.

b. *Inspect electrical cables:* Inspect the electric cables between the solar array, the charge regulator, the batteries and the refrigerator. Inspect grounding/ lightning protection. Replace any cables that are damaged.

8.6 Emergency maintenance

Follow these emergency maintenance procedures whenever an unexpected event occurs, such as a compressor failure or refrigerant leak.

Refer also to EVM-SOP-E3-01: *Responding to emergencies in fixed storage locations.*

Refer to **Annex 3** to **6** for troubleshooting checklists.

Responsibility: senior cold chain officer, RBC maintenance engineer, private contractor with long term agreement, EPI Supervisor at central, district Level, vaccinator & Head of Health Centres. *If vaccine is at immediate risk:* Protect the vaccine by temporarily moving it to another functional cold chain.

- *If the equipment is repairable:* Repair the refrigerator or freezer within seven days or as soon as possible.
- *If the equipment is beyond economic repair:* Make arrangements to obtain a replacement refrigerator or freezer as soon as possible. Dispose of the broken unit in a responsible manner.

When disposing it as a minimum:

- Remove doors or lids from refrigerators or freezers to prevent children becoming trapped.
- Recycle lead-acid batteries to prevent health hazards.
- Recycle CFC, HCFC and HFC refrigerants if applicable.

b. *Spare parts:* If spare parts have been used, update the spare parts inventory and order replacements as needed.

9. Related documents and SOPs

- EVM-SOP-E2-01: *Monitoring vaccine storage temperatures at fixed storage locations*
- EVM-SOP-E3-01: *Responding to emergencies in fixed storage locations*
- EVM-SOP-E3-05: *Looking after voltage regulators*
- EVM-SOP-E6-06: *Storing vaccine in refrigerators and freezers*
- WHO/PQS/PV01-VP2.2: *Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer – on-site checklists for completed installations*.
http://www.who.int/entity/immunization_standards/vaccine_quality/pqs_e03_pv_vp2.2.pdf
- *Logistics and cold chain for primary health care*. This series of guidance documents is now very old, but contains valuable and detailed material. In particular, refer to:
  - No. 15: *User's handbook for compression refrigerators*
  - No. 17: *User's handbook for kerosene and electric operated absorption refrigerators*
  - No. 19: *User's handbook for gas and electric refrigerators*
  - No. 20: *How to keep stocks of spare parts*

The guides are available on the PATH website at:
http://www.path.org/vaccineresources/files/FridgeRp.htm

- <Refrigerator and freezer operating and maintenance manuals>.


SDD Support package.pdf


WHO_Technician_Handbook_Part E_Tas

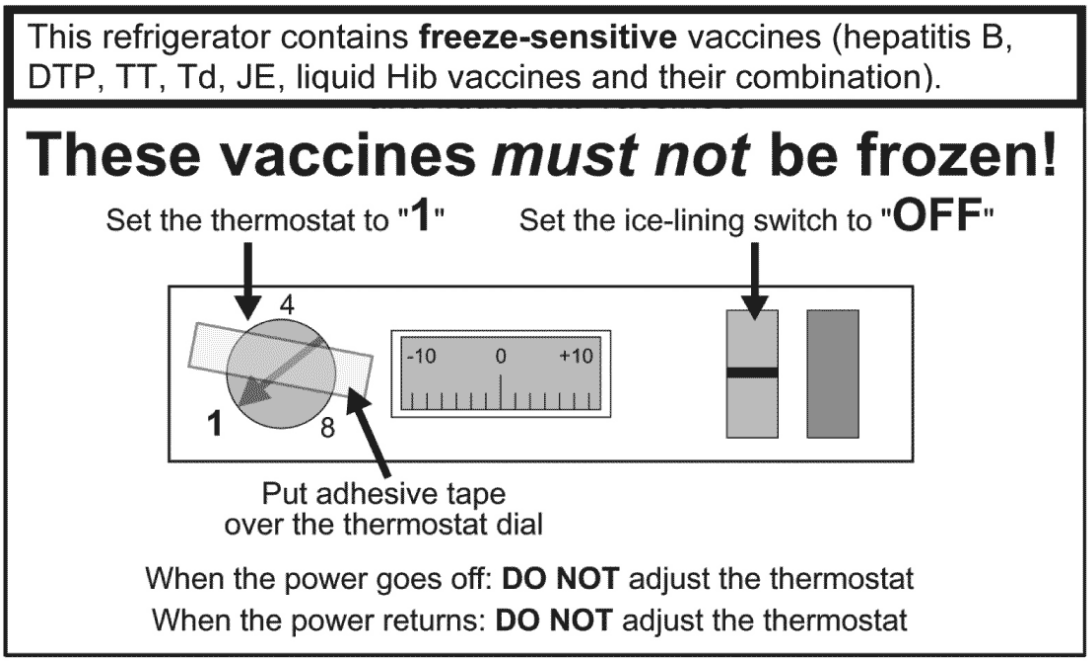

Compression refrigerators hand


WHO_EPI_LOG_88_b17.B_REV.1 Users ha

Annex 1 – Notice for ice-lined refrigerators

A notice similar to this should be fixed to older ice-lined refrigerators fitted with adjustable thermostats.

It **does not** apply to newer appliances with non-adjustable thermostats.



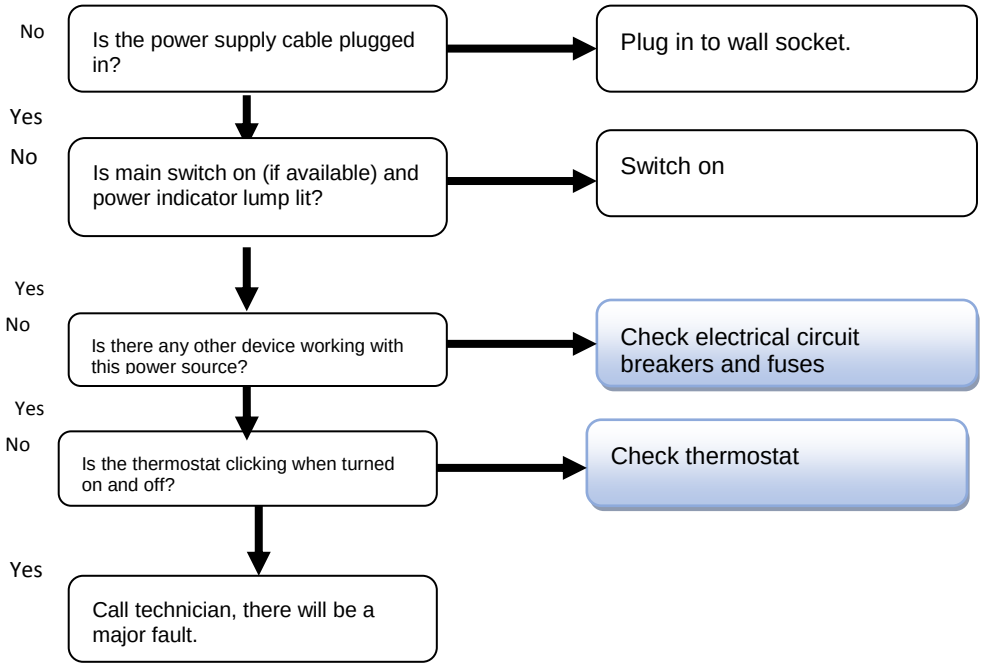
Source: WHO/IVB/04.06: *Immunization in practice - Module 3: The Cold Chain*

Annex 3 – Mains electric refrigerator troubleshooting

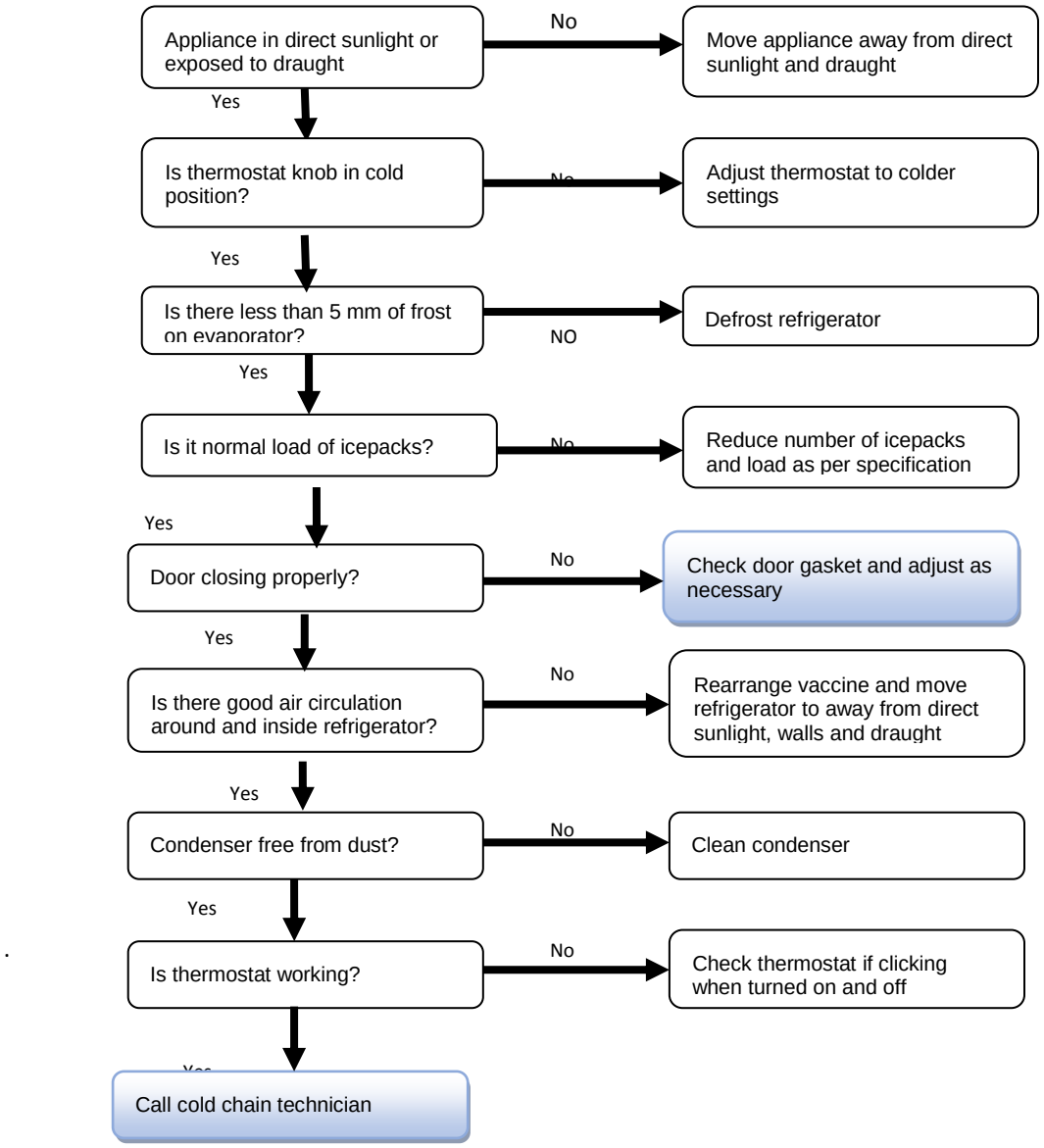
The checklists do not replace the specific instructions given in the manufacturer's maintenance manuals.

Do not carry out any of the work shown in the shaded boxes unless you have been trained to do so.

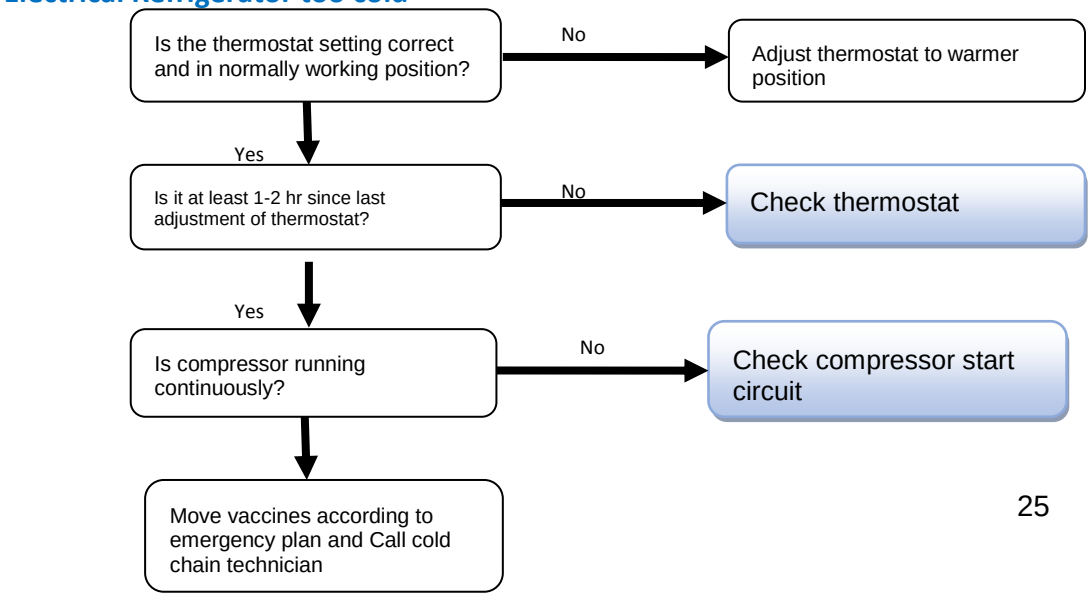
Electrical Refrigerator/Freezer does not start



Electric operated Refrigerator/freezer not cold enough

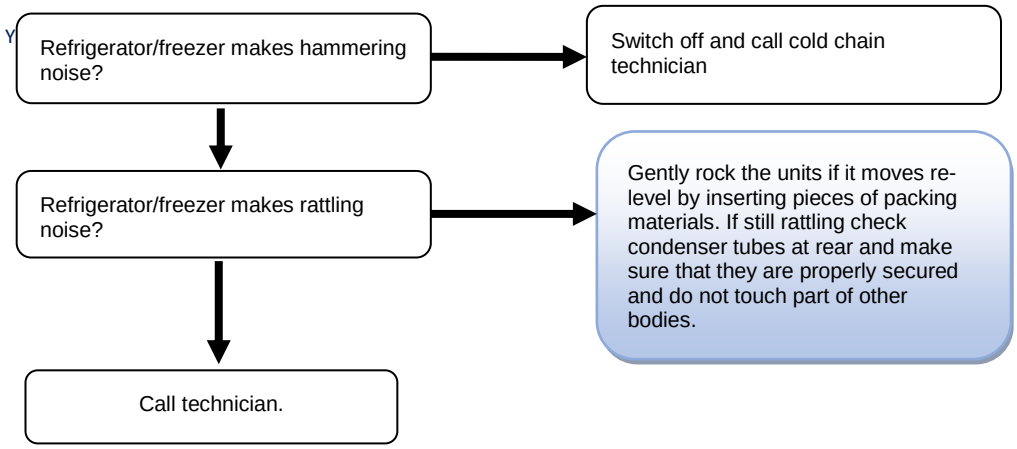


Electrical Refrigerator too cold



Yes

Refrigerator/ freezer too noisy



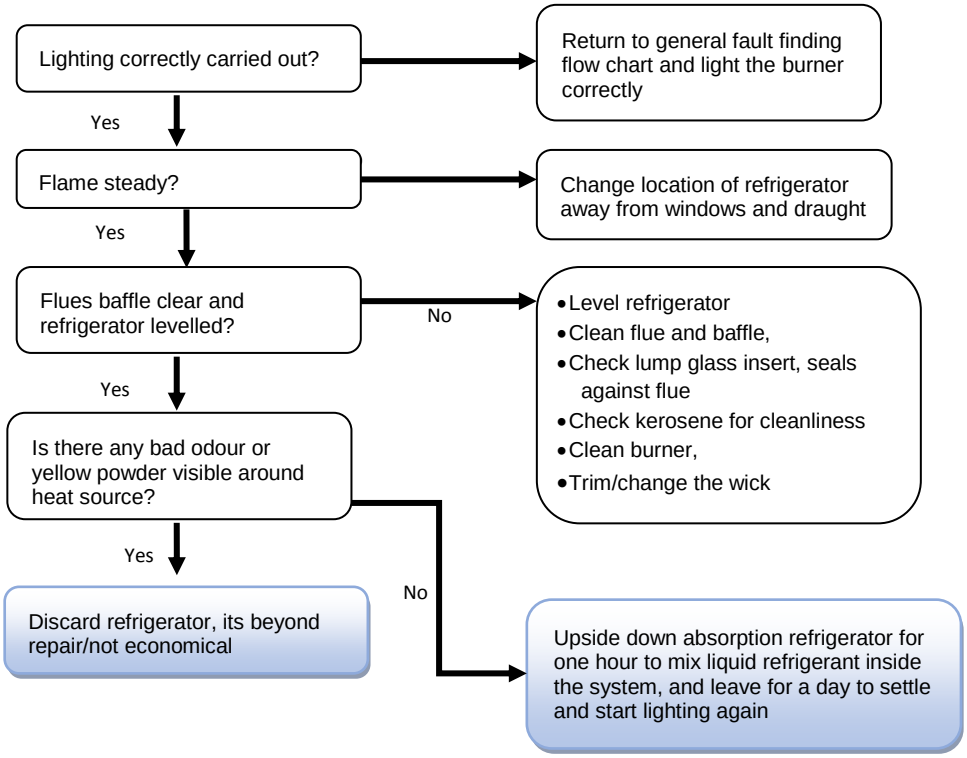
Annex 5 – Kerosene/electric refrigerator troubleshooting

The checklists do not replace the specific instructions given in the manufacturer's maintenance manuals.

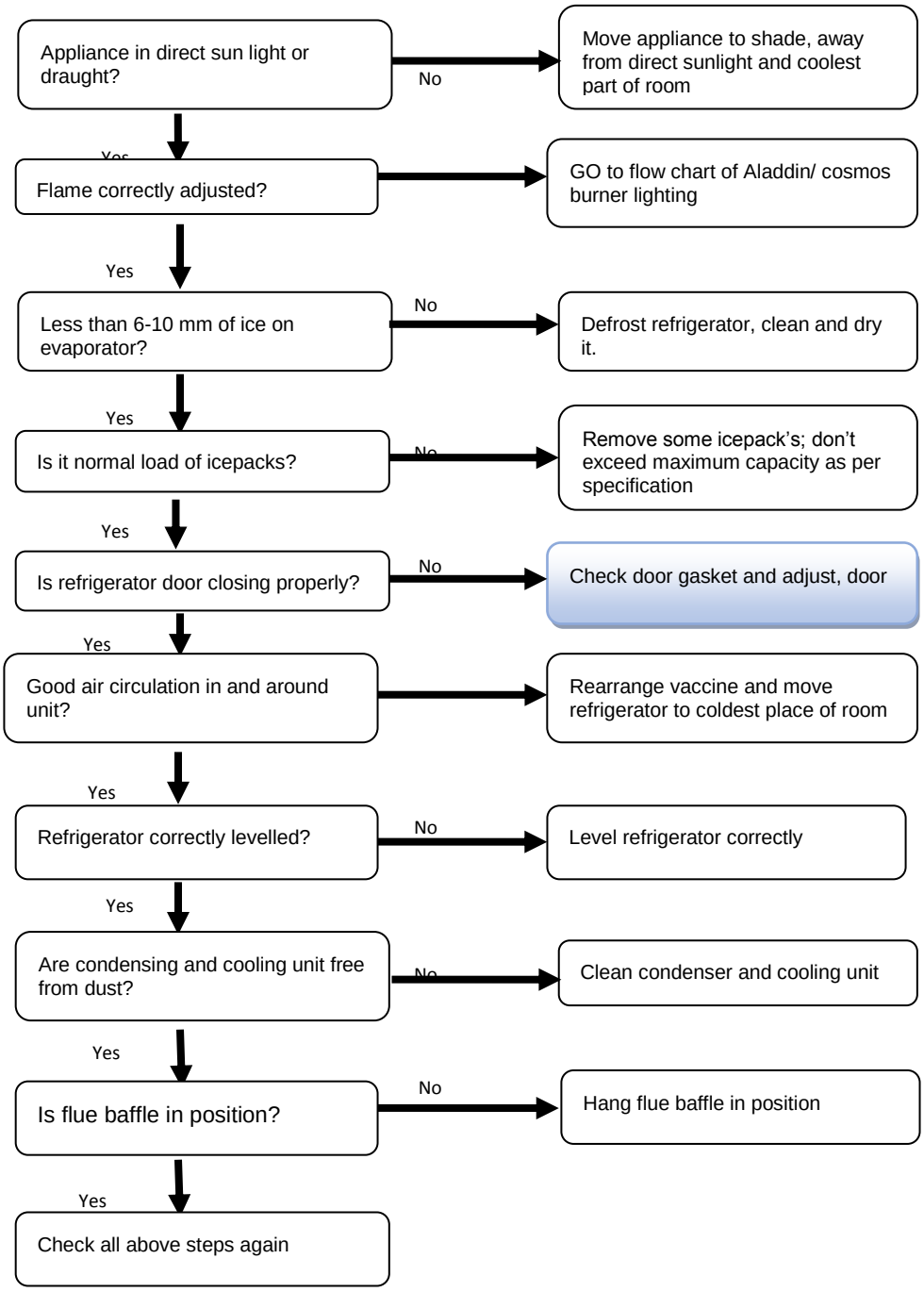
Do not carry out any of the work shown in the shaded boxes unless you have been trained to do so.

For electrical operation issues, refer to **Annex 3.**

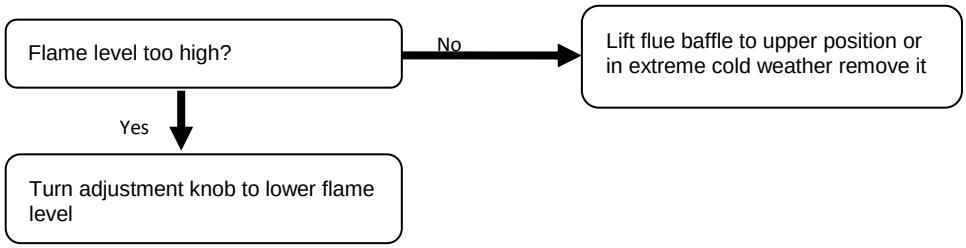
3. Refrigerator not cooling at all (Aladdin burner)



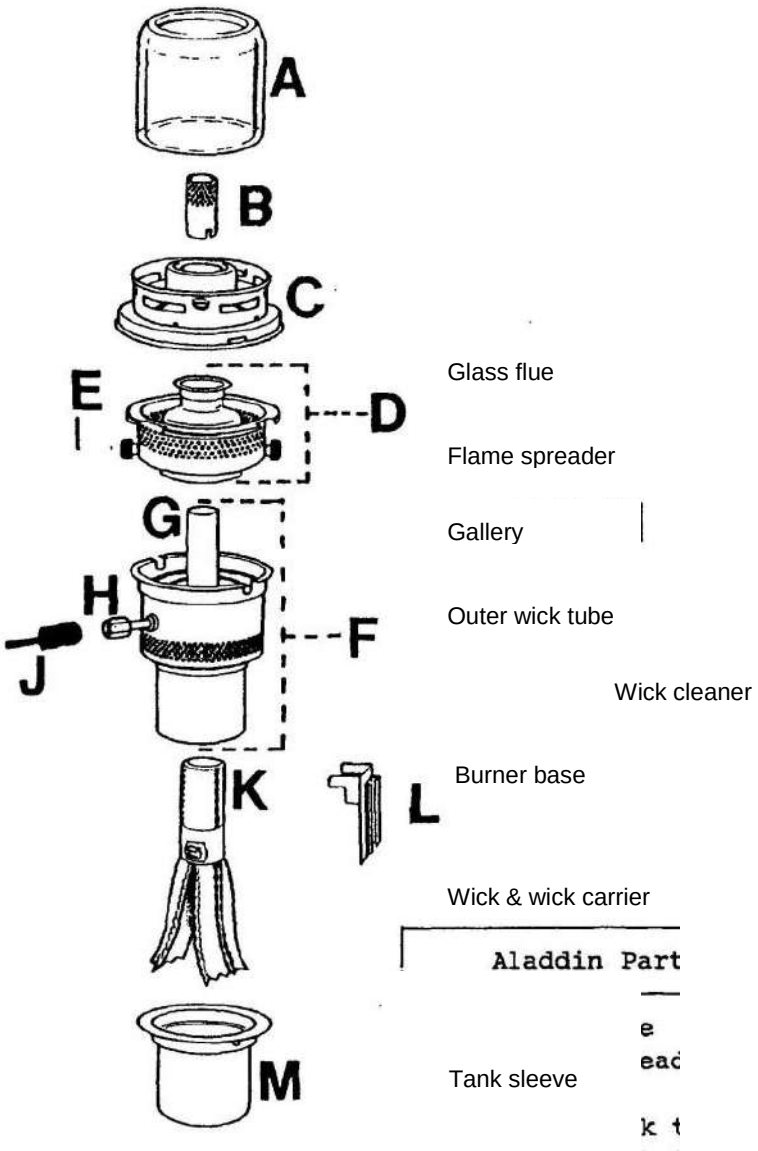
Refrigerator not cold enough(kerosene)



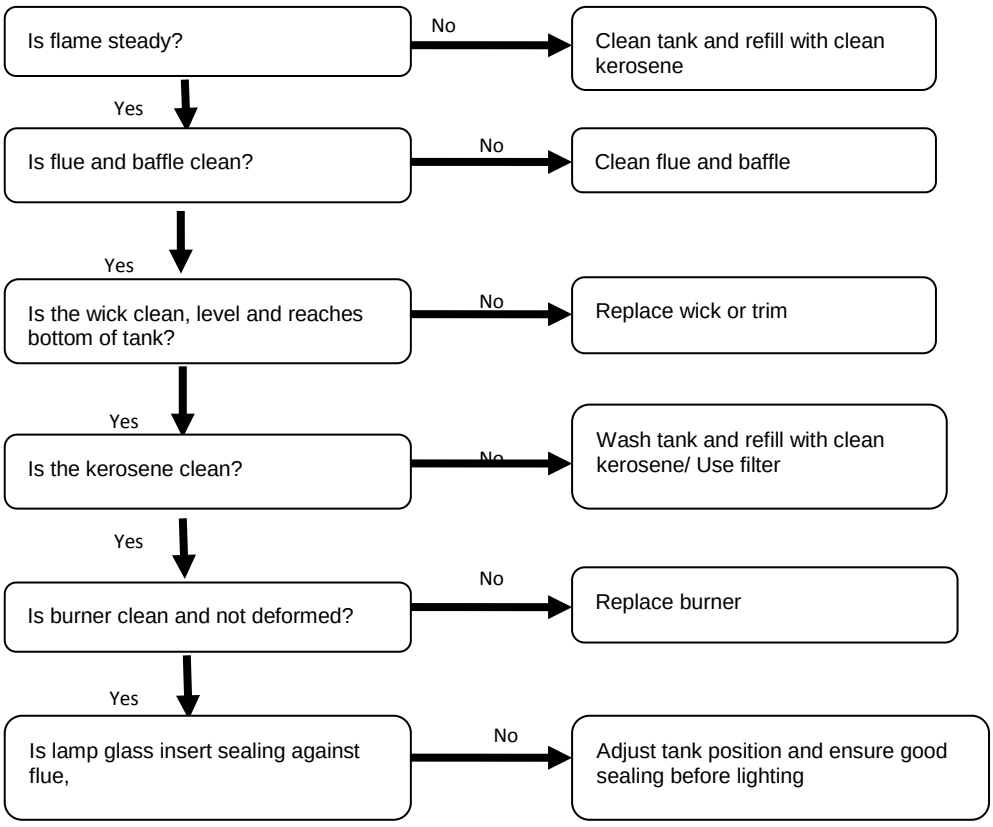
Refrigerator too cold (Kerosene operated Refrigerator)



Parts of Alladin burner



Refrigerator not cooling at all (Kosmos burner)

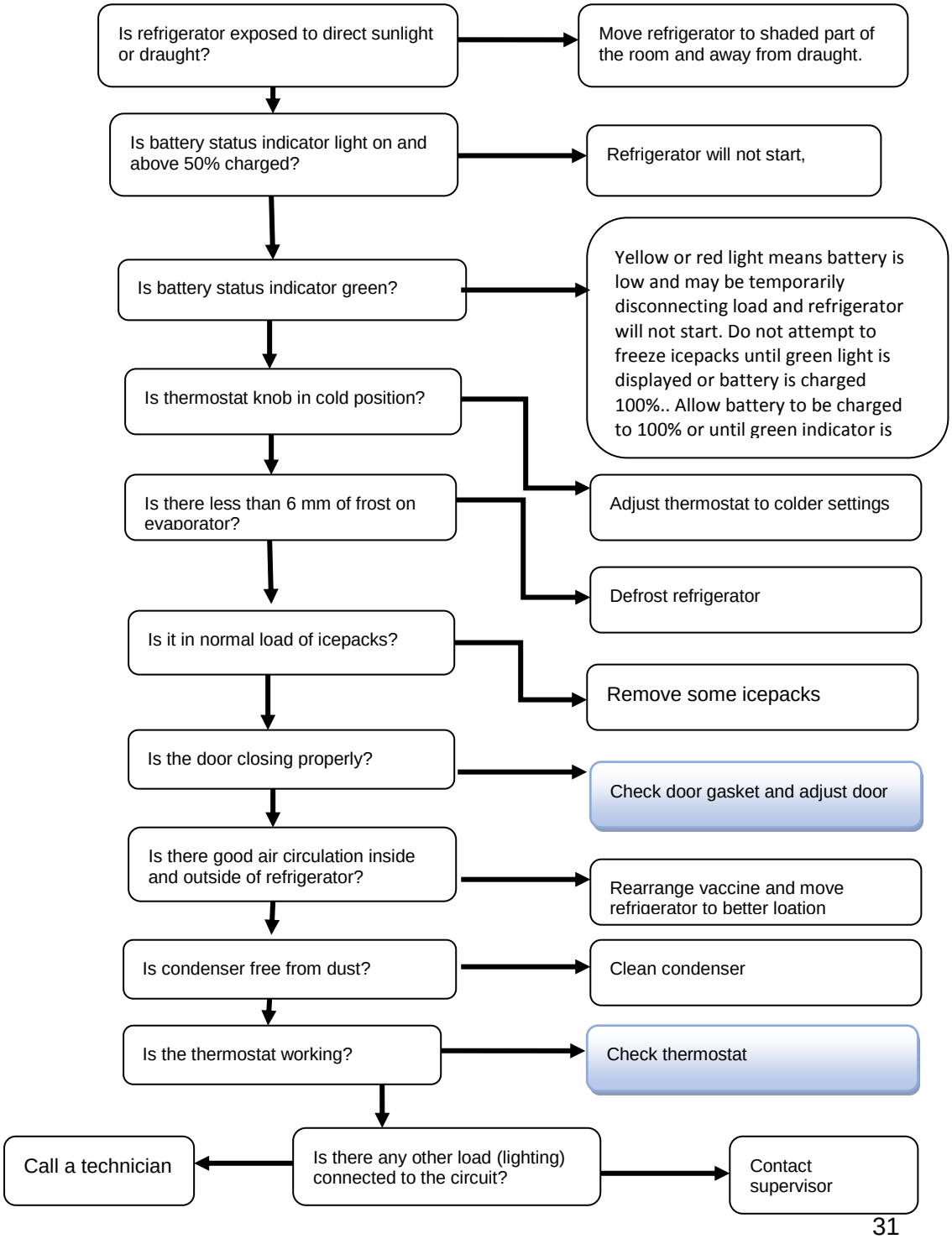


Annex 6 – Solar refrigerator troubleshooting

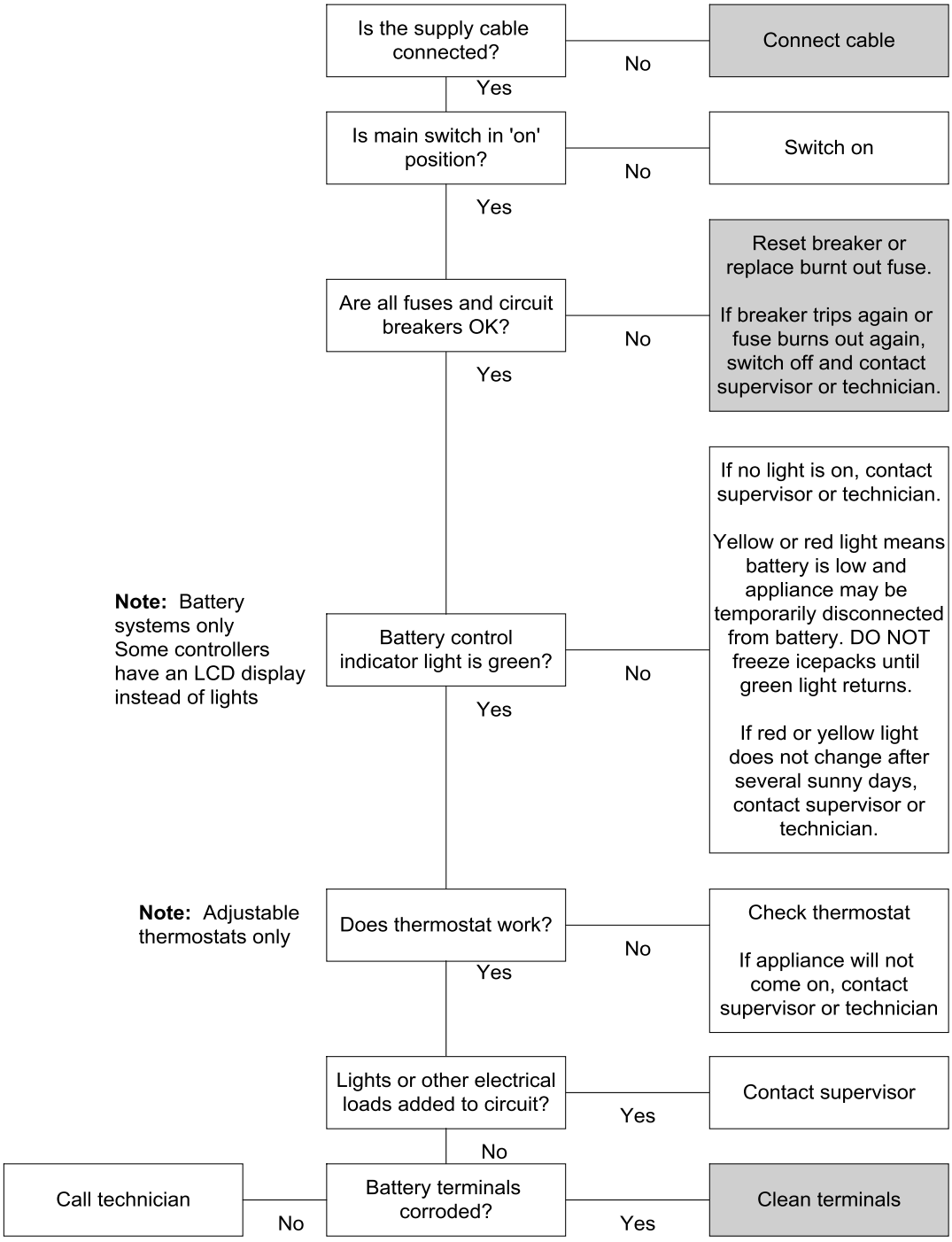
These checklists do not replace the specific instructions given in the manufacturer's maintenance manuals. It applies to standalone systems only. It does not apply to large scale photovoltaic installations designed to supply other equipment.

Do not carry out any of the work shown in the shaded boxes unless you have been trained to do so.

Solar Refrigerator not cold enough

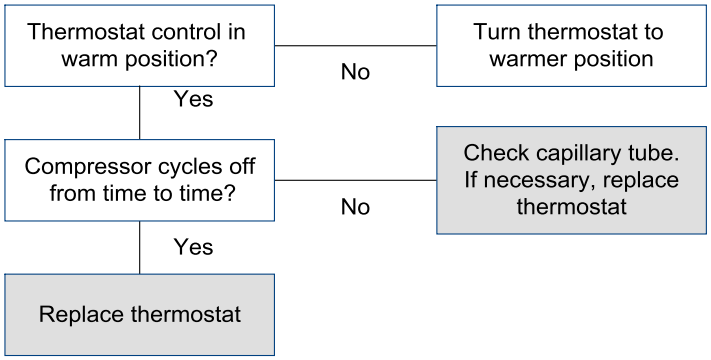


Refrigerator/freezer will not start

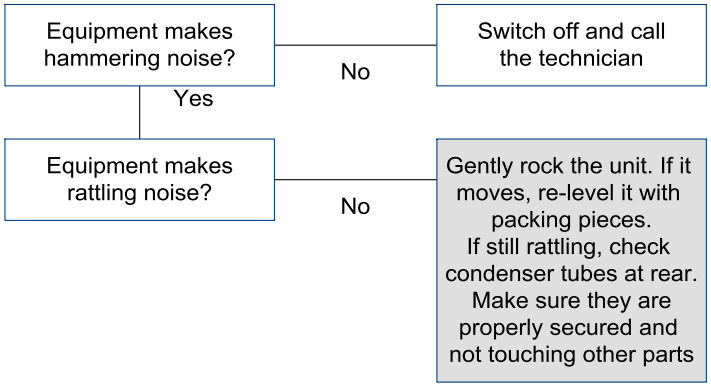


Refrigerator/freezer too cold

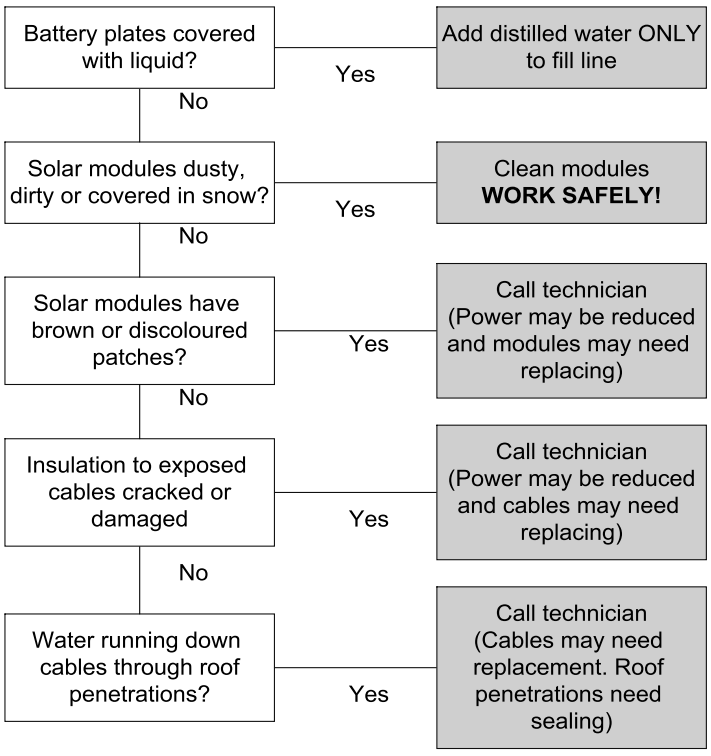
Note: Adjustable thermostats only



Refrigerator/freezer too noisy



Solar power system checklist



	Standard Operating Procedure **Looking after standby generators**		
Approvals	**Name**	**Date**	**Signature**
Authorized by:	Ministry of Health		
Reviewed by:	Rwanda, UNICEF CO	May 2016	
Revised by:	Vaccine Preventable Disease Program	October 2015	
Original author:	WHO		

Version history

No	Date	Description of change	Reason for change
1	07 Oct 2011	Original	
2	16 May 2016	Edited to context of Rwanda	
3			
4			
5			

Table of content

Distribution

Distribute this SOP to the following:

Facility type	Position(s)

Standard Operating Procedure

Looking after standby generators

10. Policy and objectives

10.1 Policy

A standby generator is a critical piece of equipment in central and district vaccine stores. Any mechanical failure which places the vaccine at risk is unacceptable and the preventive maintenance regime described in this SOP must be strictly followed.

If a mechanical failure does occur, the problem must be rectified within a maximum target periods stated in this SOP. It is essential that a sufficient stock of spare parts is maintained to ensure that these targets can be met.

All responsible personnel must know how to manage and operate the standby generator in their store.

10.2 Objectives

This SOP covers routine and emergency maintenance of fixed diesel standby generator sets. It does not cover portable models.

11. Responsibility

Responsibility for routine maintenance rests with the cold chain maintenance Engineer at Central level and biomedical technician at district level.

Responsibility for mechanical inspections, routine servicing and emergency repairs rests with cold chain maintenance Engineer of RBC and maintenance contractor at Central level and biomedical technician at district level.

12. Associated materials and equipment

Tools, spare parts and fuel. Standard form for recording generator run-time.

13. Procedure

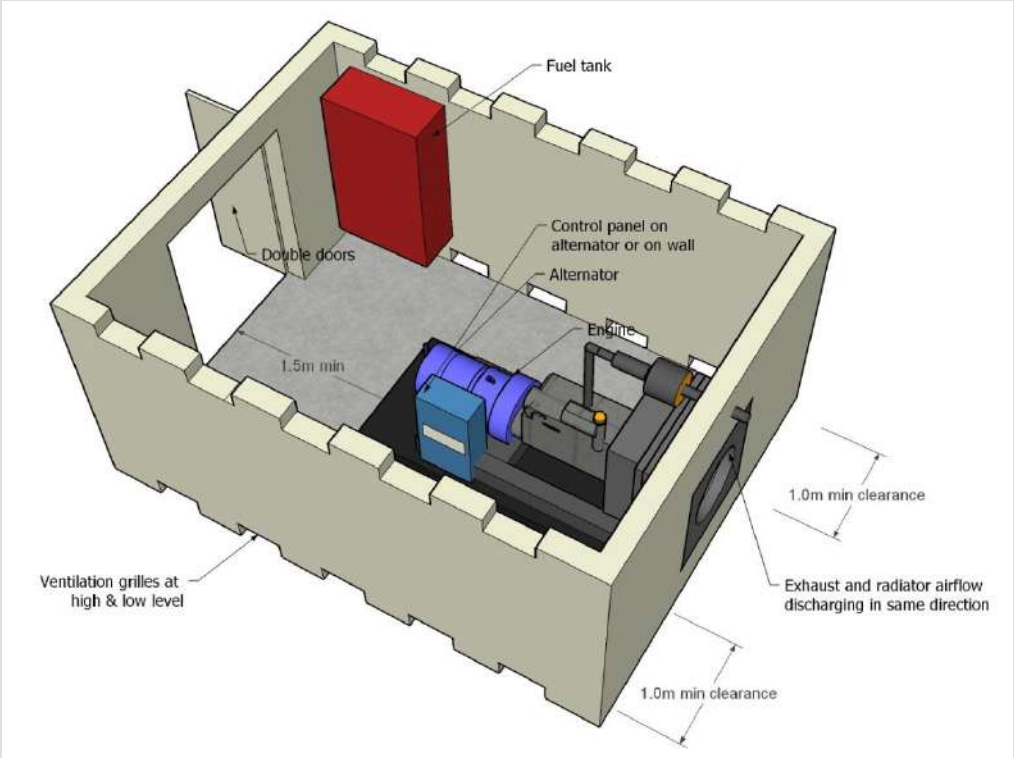
13.1 Routine maintenance

Note: This generic guidance is adapted from Intermediate Technology Publications. *Engineering in emergencies: A practical guide for relief workers,* 2001 edition. The diagram below shows the layout of a typical generator room as recommended in that document.

Depending upon the intensity of use of the generator, the tasks in 4.1.2 and 4.1.3 could be carried out daily or weekly.

The tasks from 4.1.6 onwards must only be carried out by a competent mechanic. Store personnel must receive training in the tasks from 4.1.1 to 4.1.5.

Figure 1 – Typical generator room layout



13.1.1 Record keeping

Responsible: Cold chain maintenance engineer of RBC/MTI

Responsibility:

a. Keep daily records of hours run to monitor usage and to plan servicing and maintenance schedules. See **Annex 1**. If the generator has an hour counter, you can use the counter instead of a paper record.

b. Keep records of fuel used and periodically calculate fuel consumption in litres per hour. Compare this figure with the manufacturer's rated fuel consumption. **Note:** If the fuel consumption is consistently higher than the rated consumption, there may be a problem with the engine.

13.1.2 Weekly testing

Responsible: Cold chain maintenance Engineer of RBC/MTI and Senior cold chain officer, vaccine stock management officer,

Responsibility:

a. Warn maintenance Assistant that a generator test will take place. Turn off the mains power supply to the cold store.

b. *Automatic start generators:* Wait for the generator to start automatically and check that it is operating correctly.

c. *Manual start generators:* Isolate the mains power supply. ALWAYS start the generator 'off-load'. The generator engine should be started with the alternator isolator switch in the OFF position.

d. Run the unit for five minutes

e. *Automatic start generators:* Turn the mains power supply back on. Check that the generator stops correctly.

f. *Manual start generators:* Turn the generator off. Turn on the mains power supply.

13.1.3 Engine inspection

Daily engine inspection

Responsibility: Central level, senior cold chain officer, generator operator

a. Check fuel and oil levels. Fill up as necessary.

b. *Water-cooled engines only:* Check coolant levels. Fill up as necessary.

c. Check the battery water level if applicable.

Weekly engine inspection

Responsible: Central level: Cold chain maintenance Engineer

District level: District biomedical cold chain technician

d. Check for loose nuts and bolts.

e. Check the fan belt tension, if applicable.

f. Drain water from the fuel filter/agglomerator

g. *Very dusty conditions:* Empty dust cap/bowl of dry air cleaners

13.1.4 <Daily/weekly> alternator inspection

Responsible: Central level: Senior cold chain technician

District level: District Biomedical technician

Responsibility

a. Keep alternator ventilation openings clear. Use a dry air supply to clean internally.

b. Grease alternator bearings as required.

c. Check the functioning and condition of switchgear: Relays, contactors and protection devices.

d. Check and tighten all machinery nuts and bolts, and terminals.

e. Check the condition of the mountings and frame.

f. *Brush type generators:* Check the brushes and slip rings for wear and replace if necessary.

13.1.5 Twice a week generator room cleaning

Responsible: maintenance Assistant

Responsibility:

a. Sweep the floor of the generator room and remove all rubbish.

13.1.6 After every 125 hours running

Responsible:

- Central level: Cold chain maintenance Engineer and maintenance contractor
- District level: District Biomedical technician

Responsibility:

a. Check the battery condition (if fitted).

b. *Water-cooled units:* Check for coolant leaks.

c. *Moderately dusty conditions:* Empty the dust cap/bowl and clean or replace the air cleaner element.

d. *High ambient temperatures (>35°C):* Change the engine oil and oil filter.

13.1.7 After every 250 hours running

Responsible:

- Central level: Cold chain maintenance Engineer and maintenance contractor
- District level: District Biomedical technician

Responsibility:

a. Change the engine oil and oil filter.

b. Check valve clearances.

c. Clean or replace the injectors if the exhaust smoke is black.

d. Replace the fuel filter element if using dirty fuel.

e. Check the condition or tension of drive belts (alternator, fan, etc.).

13.1.8 After every 500 hours running

Responsible:

- Central level: Cold chain maintenance Engineer and maintenance contractor
- District level: District Biomedical technician

Responsibility:

a. Replace the air filter element.

b. Replace the fuel filter element.

c. Check the exhaust and air intake for leaks, damage or restrictions.

d. Check the battery charging system, if applicable.

e. Replace the fan belt if applicable.

13.1.9 After every 1,000 hours running

Responsible:

a. Central level: Cold chain maintenance Engineer and maintenance contractor and MTI Division

b. District level: District Biomedical technician and MTI Division

Responsibility:

a. De-carbonize the engine if engine performance is poor.

b. Clean the wire gauze in the engine breather, where applicable.

13.1.10 After every 2,000 hours running

Responsible:

a. Central level: Cold chain maintenance Engineer and maintenance contractor and MTI Division

b. District level: Biomedical technician and MTI Division

Responsibility:

a. De-carbonize the engine.

b. Check the fuel injection timing.

c. Check the lubricating oil pressure.

13.1.11 After every 6,000 hours running

Responsible:

- Central level: Cold chain maintenance Engineer RBC/MTI Division
- District level: Biomedical technician and MTI Division

Responsibility:

a. Carry out a major overhaul.

13.1.12 Annual tasks

Carry out this task at least once a year at the nearest service interval.

Responsible:

- Central level: Cold chain maintenance Engineer and maintenance contractor
- District level: Biomedical technician

Responsibility:

a. *Water cooled engines:* Drain, flush and re-fill the cooling system.

13.1.13 Every five years, starting in January

Responsible: MTI Division/ Electro-mechanic Unit

Responsibility:

a. At the same time as the general safety inspection described in EVM-SOP-E5-01: *Looking after store buildings,* carry out a full safety inspection of the electrical system in the generator room, repair any defects and re-certify the system for the next five years.

13.2 Emergency maintenance

Follow these emergency maintenance procedures when an unexpected event occurs. See troubleshooting checklists in **Annex 2**. Refer also to EVM-SOP-E3-01: *Responding to emergencies in fixed storage locations.*

Responsible:

- Central level: Cold chain maintenance Engineer and maintenance contractor and MTI division
- District level: Biomedical technician and MTI Division

Responsibility

Minor defect: Rectify the defect within 24 hours and test the generator.

Major defect: Notify the electricity supply company that the standby generator is not working and that power cuts lasting more than two hours in 24 hours will place the vaccine at risk. Rectify the defect within seven days.

Major breakdown requiring generator replacement: Rent a mobile generator and make the necessary temporary connections to the control panel. Order a permanent replacement and install it when it arrives.

14. Related documents and SOPs

- EVM-SOP-E3-01: *Responding to emergencies in fixed storage locations.*
- EVM-SOP-E5-01: *Looking after store buildings.*

Annex 1– Generator run-time form

Generator run-time form																								**Sheet no:**	8
Location:		Central Medical Stores													**Inventory ID:**									GEN10	
Model:		Stamford 140 kVA													**Year installed:**									2006	
Service interval table (hours run):		125	250	375	500	625	750	875	1000	1125	1250	1375	1500	1625	1750	2000	2125	2250	2375	2500	2675	2750	2875	3000	
		3125	3250	3375	3500	3625	3750	4000	4125	4250	4375	4500	4675	4750	4875	5000	5125	5250	5375	5500	5675	5750	5875	6000	
																								Hours run at time of last service:	2005
Hours brought forward:		2065.0					**Next service due** (see service interval table):																		2125
Date	**Hours run**	**Cumulative hours run**	**Comments**																						**Initials**
3 Jun 2011	1.5	2066.5	Mains failure																						EB
5 Jun 2010	0.5	2067.0	Weekly test																						FC
Hours carried forward:																									

Note: Use comments column to record reason for running and routine and emergency service and repair actions. Use *service interval hours* table to identify time of next service.

Annex 2 – Troubleshooting checklists

Larger generators often come with a control panel for auto-start, either designed independently of the actual generator set, or procured with it. Defects caused by the failure of control panel electronics (fuses, relays, internal clocks, etc.) are not specifically covered by the checklists below – for this type of fault, refer to the panel manufacturer's instructions and wiring diagrams.

Checklist 1: Generator problems

Symptom	*Possible causes*
No generator output	• Faulty or loose terminals, disconnected wiring or dirty contacts • Blown fuse or tripped circuit breaker caused by: - Overloaded generator - Short circuit due to breakdown in cable insulation • Break in stator output coil • Demagnetized permanent magnet • A faulty automatic voltage regulator (AVR) • *Brush type generators only:* Worn or dirty brushes and slip rings.
Output voltage is very low (only a few volts)	• A faulty AVR • *Brush type generators only:* - Disconnected rotor coil - Worn brushes or faulty contact
Output voltage is low but more than a few volts	• Engine speed too low – adjust • Short circuit in a coil • A faulty AVR
Output voltage is high at normal engine speed	• A faulty AVR
Output voltage is normal when the generator set is cold, but varies when the set warms up	• A faulty AVR
Generator trips out, or rated generator output is not available and the speed of the engine fluctuates significantly (>10%) between no-load and load conditions	• Excessive initial current at start up: reduce load by: - Starting higher loads first - Fitting reduced voltage starting equipment • Output of engine is below rated engine power: service and/or repair the engine. • Faulty engine governor
Engine problems	• See **Checklist 2 and 3**.
Warning: • DO NOT change fuses or re-set circuit breakers without first isolating the supply, stopping the generator and correcting the fault. • DO NOT attempt to start a generator with an electrical load connected.	

Source: Intermediate Technology Publications. *Engineering in emergencies: A practical guide for relief workers.* 2001 edition. Table 14.3.

Checklist 2: Symptoms and possible causes of faults in diesel engines

Symptom	*Possible causes (**Checklist 3**)*
Difficult starting: • Engine turns over, but will not fire – fuel problem • Engine will not turn over, or only slowly – cranking problem • Engine turns easily – poor compression • Engine will not bring generator up to speed – lack of power	 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 12, 15, 16, 17, 18 19, 20, 21, 22, 23, 24, 25, 26, 30 Poor compression, fuel problems and overheating, plus: 27, 28, 29, 30, 56
Engine misfires	Poor compression, fuel problems and overheating, plus: 4, 5, 6, 8, 9, 28, 29
Engine runs, then stops	Fuel problems, poor compression, overheating plus: 14, 31
Engine fails to attain running speed	6, 10, 15, 31, 53
Engine 'hunts' (speed varies up and down around a mean)	6, 8, 9, 53
High fuel consumption	Poor compression, plus: 1, 8, 9, 11, 20, 23, 24, 26, 27, 28, 29, 30, 56
High oil consumption	21, 23, 24
Dark blue exhaust smoke	23, 24
White exhaust smoke	7, 32
Black exhaust smoke	1, 8, 11, 31, 33
Excessive carbon deposits on piston head, cylinder head and in exhaust	1,8, 11, 27, 28, 54, 55, 56
Overheating: • Air-cooled engines • Water-cooled engines	 14, 28, 31, 34, 35, 44 14, 28, 31, 36, 37, 38, 39
Low oil pressure	13, 14, 40, 41, 42, 43
High oil pressure	43
Vibration	Poor compression, plus: 8, 9, 20, 24, 44, 45, 46, 47
'Knocking' (detonation)	Overheating, plus: 1, 8, 28, 52
Mechanical noises	23, 26, 46, 47, 48, 49, 50, 51, 52

Source: Intermediate Technology Publications. *Engineering in emergencies: A practical guide for relief workers.* 2001 edition. Table 13.6.

Checklist 3: Possible causes and remedies of faults in diesel engines

*Possible causes (see **Checklist 2**)*		*Possible remedies*
1	Incorrect grade, or poor quality fuel	Change fuel
2	Fuel tank empty	Fill tank and bleed fuel system of air
3	Stop/start lever in wrong position	Adjust
4	Choked fuel filter – visually inspect	Poor servicing – change filter
5	Faulty fuel lift pump	Inspect and repair
6	Air in fuel system	Bleed air from system
7	Water in fuel system	Drain fuel system, including filter bowl, agglomerator and tank
8	Faulty injector nozzle	Test spray and clean or change nozzle
9	Faulty fuel injection pump	Have pump checked by competent workshop
10	Retarded injection	Check and adjust
11	Choked air filter	Poor servicing – clean or replace
12	Lubricating oil too heavy	Change oil
13	Lubricating oil too thin	Change oil
14	Lubricating oil level low	Poor servicing – top up
15	Engine started under load	Disengage load at clutch
16	Battery not charged (electric start)	Charge battery, or 'jump-start'
17	Loose or corroded battery terminals	Check, clean and tighten
18	Faulty starter motor (electric start)	Check terminals, solenoid switch, starter gear, brushes
19	Loose injector	Check and tighten
20	Valves leaking or sticking	Clean and re-grind. Reset tappets
21	Valve guides worn	Replace guides
22	Broken or defective valve spring	Replace spring
23	Worn cylinder bore: excessive piston clearance gives a continuous 'slapping' noise	Re-bore and fit with oversized piston and rings
24	Broken, worn or sticking piston rings	Clean and free rings. Check cylinder liner is not scored
25	Incorrect decompressor clearance	Inspect and adjust
26	Incorrect tappet clearance	Check and adjust
27	Choked exhaust system	Clear or replace
28	Incorrect injection pump timing	Check and re-time
29	Incorrect valve timing	Re-set valve timing
30	Cylinder head gasket leaking	Check and replace
31	Engine overloaded	Reduce load
32	Water leaking from the cooling system into the cylinder combustion area	Check and replace gasket
33	Inlet air temperature high	Improve ventilation to engine housing and airflow to and from the engine
34	Poor circulation of cooling air • Re-circulated cooling air • Air inlet and/or outlet obstructed	As 33 above
35	Cylinder cooling fins blocked	Clean
36	Water cooling thermostat faulty	Check and replace
37	Cooling water level too low	Top up

*Possible causes (see **Checklist 2**)*		*Possible remedies*
38	Slack water pump drive belt	Inspect drive belt for wear. Tighten or replace
39	Blockage in water cooling system	Clear with cleaning fluid additive
40	Choke oil strainer or filter	Clean strainer or change filter
41	Badly worn bearings	Overhaul
42	Worn oil pump or damaged drive	Check and replace
43	Defective oil pressure relief valve	Repair or replace
44	Piston seizure	Stop engine immediately
45	Damaged cooling fan	Reshape or replace
46	Loose or damaged engine mountings	Inspect, tighten or change
47	Loose flywheel – intermittent 'thuds'	Check and tighten
48	Worn connecting rod bush or bearing – low pitched 'knock'	Overhaul
49	Worn gudgeon pin or small end bearing – high pitched 'tap'	Overhaul
50	Main bearing worn – low pitched 'thud'	Overhaul
51	Crankshaft end play – intermittent 'thuds'	Adjust
52	Excessive carbon build-up on piston	De-carbonize
53	Incorrectly adjusted governor or tight governor linkages	Adjust
54	Continuous idling	Shut down instead of idle
55	Regular running on low load	Match engine to load by choosing a lower powered generator set.
56	Low temperature running	Check sizing and operation of cooling system – especially water-cooled engines.

Source: Intermediate Technology Publications. *Engineering in emergencies: A practical guide for relief workers.* 2001 edition. Table 13.7.

	Standard Operating Procedure **Looking after voltage regulators**		
Approvals	**Name**	**Date**	**Signature**
Authorized by:	Ministry of Health		
Reviewed by:	Rwanda, UNICEF CO	May 2016	
Revised by:	Vaccine Preventable Disease Program	October 2015	
Original author:	WHO		

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1	07 Oct 2011	Original	
2	16 May 2016	Edited to context of Rwanda	
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Distribution

Distribute this SOP to the following:

Facility type	Position(s)

15. Policy and objectives

15.1 Policy

Responsible personnel should know how to obtain advice on the stability of the power supply. This advice can be obtained from the power authority or from a competent electrical engineer. Voltage regulators are essential wherever voltage fluctuations exceed ± 15%, or exceed the tolerance allowed by the refrigeration equipment manufacturer. If regulators are not fitted, the refrigeration equipment will suffer permanent damage and vaccine may be lost.

15.2 Objectives

This SOP tells you how to carry out routine checks on the three-phase voltage regulators that are connected to the cold rooms and freezer rooms. It also tells you how to check whether the single-phase voltage regulators connected to individual vaccine refrigerators and freezers are working.

Note: This SOP describes how to check one particular model of three-phase voltage regulator (Electrogard Servo Voltage Stabilizer). **The procedure must be adapted to suit the specific characteristics of the equipment installed in each facility**. For example, the ±1% control tolerance describe in section 4.1.1 is a characteristic of the Electrogard equipment described. Other products may be different.

16. Responsibility

Vaccine stock management officer should carry out daily checks for functionality. RBC/MTI engineer has primary responsibility for servicing the 3-phase units and senior cold chain officer.

17. Associated materials and equipment

Tools and spare parts.

18. Procedure

18.1 Training

Responsibility: RBC/MTI engineer.

All personnel who are responsible for looking after voltage regulation equipment should receive appropriate hands-on training to ensure that they are capable of carrying out all of the tasks set out in this SOP.

18.2 Manuals

Responsibility: RBC/MTI, senior cold chain officer, vaccine stock management officer.

Read the manufacturer's operating instructions and follow them exactly. File the instruction manuals in a safe place.

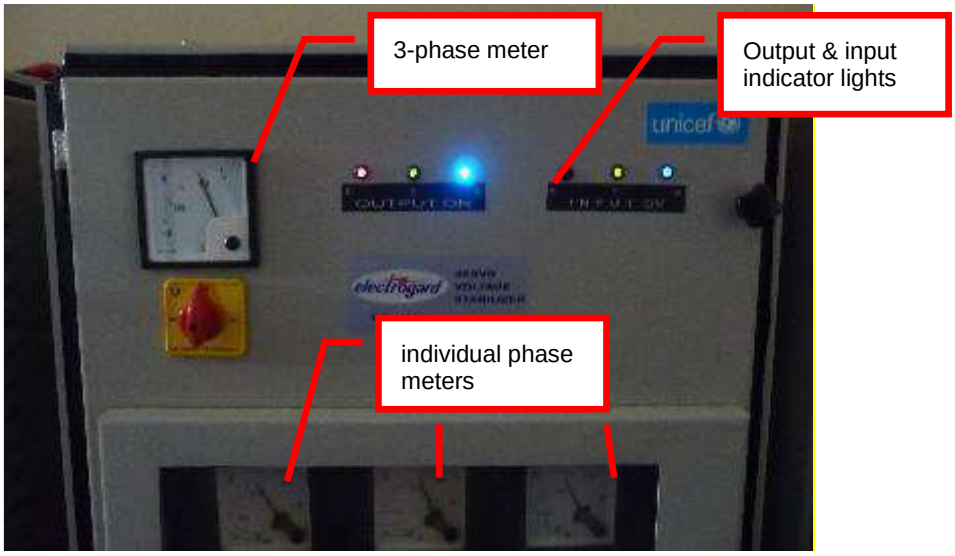
18.3 Daily checks

Carry out the checks described below at the same time as the morning temperature monitoring check. See EVM-SOP-E2-01: *Monitoring vaccine storage temperatures at fixed storage locations*.

18.3.1 Three-phase voltage regulators for cold rooms and freezer room

Responsibility: Senior cold chain officer, vaccine stock management officer

a. Check that the 3-phase meter is reading 400 volts ±1% (396-404 volts) and check that the three individual phase meters on the lower panel are all reading 230 volts ±1% (228-232 volts). If they are not, call the <list responsible maintenance personnel>.



b. Check that all three red yellow and green 'output' phase indicator lights and all three red yellow and green 'input' phase indicator lights are on. If they are not, call the <list responsible maintenance personnel>.

c. Listen to the units. If you hear a 'chattering' sound, call the <list responsible maintenance personnel>.

18.3.2 Single-phase refrigerator and freezer voltage regulators

Responsibility: Senior cold chain officer

a. Make sure that the correct type of unit is connected the refrigerator or freezer. Electric compression cycle equipment requires one type of unit.

b. Check that the input and output indicator lights on each of the units are showing correctly.

c. If the unit is defective, replace it as soon as possible.

18.4 Troubleshooting the Electrogard units

Responsibility: Senior cold chain officer, RBC cold chain engineer

a. If problems are reported, follow the Electrogard troubleshooting checklists shown in **Annex 1** and consult the Electrogard installation manual. Take suitable electrical safety precautions whilst carrying out this work.

b. If spare parts are required, or spare parts have been used – for example, carbon brushes, request the senior cold chain officer, EPI manager to order replacements.

19. Related documents and SOPs

- EVM-SOP-E2-01: *Monitoring vaccine storage temperatures at fixed storage locations*.

Annex 1 – Electrogard troubleshooting checklist

The following notes and troubleshooting tables have been supplied by Electrogard. The work shown on the troubleshooting tables must only be carried out by a qualified electrician.

Control panel indicators and switches

1. Each phase voltage can be selected by turning the yellow rotary switch mounted just below the main voltmeter on the top left hand corner of the front panel. This enables R-Y, Y-B and B-R voltages to be read on the voltmeter. These voltages should always be 400 volts ±1% (396-404 volts). In addition, the individual Phase to Neutral voltage is shown on the three single phase meters behind the central glass panel. Each Phase to Neutral voltage should be 230 volts±1% (228-232 volts).
2. Three input indicators - Red, Yellow and Green - indicate availability of three phases from the mains commercial supply to the regulator. If any one of the phases is missing, the indicator of that phase will switch-off and the regulator will trip and show zero output voltage. In such a case, your electrician needs to check and ensure that all the three phases are made available to the regulator from the commercial supply and that nothing is wrong with the regulator.
3. Three output indicators - Red, Yellow and Green indicate availability of all the three phases, properly stabilized, to the cold room or freezer room. If the regulator trips due to any fault, these three output indicators will switch-off simultaneously. This could be due to excessively high input voltage in one or more of the phases, or any phase missing, or a fault with the regulator.
4. These regulators are protected against high voltages and single phasing resulting in output voltage trip in both the cases. The overloading/ short circuit protection is provided by an MCB in the input circuit and located on the right side panel.

Servo Voltage Stabilizer Maintenance/ Trouble Shooting Manual

If the Servo Voltage Stabilizer is not giving satisfactory service, please check and do the necessary adjustments as suggested below:

FAULT	SOLUTION
1) MAINS ARE GIVEN TO SERVO BUT NO OUTPUT VOLTAGE FROM SERVO.	• CHECK THE INPUT CONNECTIONS, IF LOOSE TIGHTEN THEM. • CHECK THE MCB ON SIDE PANEL, WHETHER ON OR NOT. • CHECK THE CONTACTOR WHETHER ON OR NOT. IF NOT CHECK THE PRESENCE OF VOLTAGE ON THE CONTACTOR COIL, IF PRESENT – COIL IS DEFECTIVE – REPLACE CONTACTOR COIL. • CHECK IF THE INPUT VOLTAGE IS WITH IN THE SPECIFIED WINDOW. IF OUTSIDE THE WINDOW, THE STABILIZER IS IN CUT-OFF MODE.
2) OUTPUT VOLTAGE IS NOT AT 230 VOLTS IN ONE OR TWO PHASES	• OPEN THE FRONT PANEL. SET THE VOLTAGE FROM 'POT', AFTER REMOVING THE CAP, WHERE SET-VOLTAGE IS WRITTEN, BY ROTATING CLOCK OR ANTI CLOCK WISE WITH SCREW DRIVER. • IF COULD NOT BE SET FROM POT, SET THE VOLTAGE FROM PRESET NO. P1 ON THE CARD BY ROTATING IT WITH SCREW DRIVER.
3) SERVO MAKES CHATTERING SOUND WHILE CORRECTING VOLTAGE.	• THE SESTIVITY PRESET P-2 ON THE CARD WILL SOLVE THE PROBLEM. ROTATE IN CLOCKWISE OR ANTI CLOCK -WISE SLOWLY. • CHECK THE SENSTIVITY BY INCREASING THE VOLTAGE MANUALLY & THEN PUTTING IT ON AUTO MODE. NOW DECREASE THE VOLTAGE & PUT ON AUTO MODE & SEE WHETHER THE SAME SOUND IS THERE OR NOT. ALSO CHECK THAT THE OUTPUT VOLTAGE COMES TO 230±1% VOLTS IN BOTH CASES, OTHERWISE ADJUST P2 AGAIN.
4) OUTPUT CUT OFF PROBLEM AT LOW / HIGH VOLTAGE.	• ADJUST PRESET ON THE CARD. P-3 IS FOR SETTING LOW VOLTAGE CUT OFF & PRESET P-4 IS FOR SETTING HIGH VOLTAGE CUT OFF.

FAULT	SOLUTION
5) OUTPUT IS ZERO IN ONE PHASE & DOES NOT INCREASE OR DECREASE MANUALLY.	• CHECK THE CARBON BRUSH OF VARIABLE TRANSFORMER (VARIAC) IF BROKEN, CHANGE IT. SPARE CARBONS ARE IN THE ARM ITSELF UNDER THE ALUMINIUM COVER.
6) METER IS NOT SHOWING INPUT OR OUTPUT VOLTAGE.	• CHECK THE METER SWITCH IS ON OR NOT. • METER MAY BE DEFECTIVE IF NOT SHOWING INPUT AS WELL AS OUTPUT. • THE SELECTOR SWITCH MAY BE FAULTY, CHANGE IT.
7) VOLTAGE IS SET ON EACH PHASE AT 230 VOLTS BUT BETWEEN R-Y, Y-B & B-R, i.e., BETWEEN PHASE TO PHASE IS NOT 400 VOLTS AS REQUIRED OR DIFFERS WITH EACH OTHER.	• TIGHTEN THE NEUTRAL ON ALL THE VARIACS & INPUT/ OUTPUT TERMINALS. • IT IS ADVISABLE TO HAVE A DEDICATED EARTH DUG UP FOR GROUNDING THE NEUTRAL. THE SERVO CHASSIS SHOULD HAVE A SEPARATE EARTH.

SAGAR ELECTRICALS
14A Industrial Estate, Ambala Cantt – 133001, Haryana, India
www.electrogard.com

	Standard Operating Procedure **Using computerized stock management systems**		
Approvals	**Name**	**Date**	**Signature**
Authorized by:	Ministry of Health		
Reviewed by:	Rwanda, UNICEF CO	May 2016	
Revised by:	Vaccine Preventable Disease Program	October 2015	
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1	07 Oct 2011	Original	
2	16 May 2016	Edited to context of Rwanda	
3			
4			
5			

Standard Operating Procedure

Using computerized stock management systems

20. Policy and objectives

20.1 Policy

Where a computerized stock control system is used, the software and computer equipment must be suitable for the task and well-maintained and responsible personnel must know how to use the system. In particular:

a. The computer system running the software must be kept free of computer viruses.

b. Data files must be backed up on monthly basis and the backup media must be kept in a safe place.

c. Stock records must be accurate and up-to-date.

d. Programme managers must receive regular reports on the status of vaccines and other immunization supplies.

20.2 Objectives

This SOP describes how to achieve these policy requirements. It does not describe the detailed use of the stock control software. This is covered by the software manual and the associated training course.

21. Responsibility

22. Vaccine Supply Chain Officer, stock management officer, IT personnel.

23. Associated materials and equipment

Computer system, software and peripherals required to run the stock control program (stock management tool).

24. Procedure

24.1 Managing and protecting the stock control computer system

Responsibility: Vaccine Supply Chain Officer, stock management officer, IT personnel

a. The computer system must be fitted with a voltage regulator and an uninterrupted power supply (UPS) device[8].

[8] If a laptop is used, the UPS function could be performed by the laptop battery. However, the use of laptops raises other security issues.

b. The computer system must have a broadband internet connection which is password-protected and permanently connected during working hours.

c. A high quality anti-virus and malware package must be installed and the subscription(s) for updates must be fully funded and paid for as routine recurrent expenditure. The software must be configured to download updates whenever the computer is connected to the internet, and to carry out automatic anti-virus and anti-spyware scanning on a weekly basis.

d. The system administrator must ensure that the system firewall is properly configured. All ports not commonly used to browse the internet should be blocked; preferably only those ports that essential for managing the stock management process should be enabled.

e. Only the approved software packages which are directly related to the task of managing the vaccine store may be loaded onto the computer.)

f. The computer must be password-protected. Only the Vaccine Supply Chain Officer, cold chain senior officer, stock management officer and vaccination program manager should have administrative privileges and be allowed to install software and software updates (excluding automatic anti-virus updates).

g. Change the default password supplied with the stock control software. Update the password at least once a year, and whenever there is a change of store personnel.

h. Ensure that 'strong' passwords are used: for example **Hello** is a 'weak' password; combinations of letters and numbers such as **Hello4352** are better; random characters such as **45%hk^!d4f7** are 'strong'.

i. Always use an agreed date format –, dd/mm/yyyy

j. Virus propagation and general security breaches can be reduced by disabling Internet Explorer and using Mozilla Firefox as the default web browser.

k. Only officially authorized backup devices may be attached to the computer. No unauthorized USB key (flash drive device), CD, DVD or external hard disc should be used at any time. Only the cold chain senior officer should be able to authorize the use of these devices. If a request is made for an electronic copy of the stock control database or reports, these must be sent by email.

l. Keep the software installation CD in a safe place. Configure the stock control software so that it produces routine reports in a format that meets the needs of the Vaccination program

Reasons:

- To ensure that the computer system is fully protected against power failure and computer viruses.
- To prevent unauthorized access.

24.2 Data to be recorded

Responsibility: Vaccine supply chain officer.

The following mandatory information must be registered in the stock control system whenever a shipment of vaccine or other immunization supplies is received:

Vaccines:

a. Type of vaccine.
b. Manufacturer of the vaccine.
c. Vial presentation (doses per vial).
d. Batch number(s).
e. Expiry date.
f. Number of doses received.
g. VVM stage.
h. Name of cold chain equipment where the vaccine is kept – for example: Cold Room # 1.

Diluents:

a. Type of vaccine for which the diluent is intended.
b. Manufacturer of the diluent.
c. Vial presentation (doses per vial).
d. Batch number(s).
e. Expiry date.
f. Number of doses received.
g. Name of store where the diluent is kept.

Syringes:

a. Type description.
b. Manufacturer of the syringe.
c. Batch number(s).
d. Expiry date.
e. Quantity received.
f. Name of store where the syringes are kept.

Other supplies:

a. Type description.
b. Manufacturer of the product.
c. Batch number(s) if applicable.
d. Production date or expiry date, if applicable[9].
e. Quantity received.
f. Name of store where the item is kept.

[9] For example, FridgeTag™ devices have a production date on the back and must be distributed and activated within one year of this date.

24.3 Every Week

Responsibility: Supply chain officer,

a. Process all stock arrivals and dispatches using the stock control software. No transactions may be made outside the stock control system and no supplies must leave the store without an Issue Voucher generated by the stock control software.
b. Ensure that full details of all transactions are completely entered immediately they occur.
c. Backup the database at the end of the week ALWAYS click on the Windows 'Safely Remove Hardware' function before removing the flash drive from the USB port. ONLY use these flash drives for stock control backups; do not use them for any other purpose.
d. Keep the two flash drives in a locked drawer or cupboard. Email a copy of the backup to EPI manager at the end of each working week.
e. Respond immediately to all anti-virus software update instructions.

Reasons:

- To ensure that stock records are always up-to-date.
- To ensure that backups are never more than two working days old, even if one of the flash drives fails.
- To ensure that the anti-virus software is up-to-date.

24.4 Every month

Responsibility: Vaccine stock management officer and Vaccine supply chain officer

Print the following reports from stock control system and send them to your supervisor latest on every 5th for the following month:

a. *Current stock reports* for all vaccines, diluents, syringes and all other supplies.
b. *Stock out date report* estimating how long current stocks will last.
c. *Monthly dispatches report* for the previous month for all items kept in the store.
d. *Vaccine by Recipient/Activity report* for the previous month.
e. Keep hard copies of all these reports in the filing system.

Note: The names of these reports vary from system to system – amend the list to include the relevant reports for the system installed.

Responsibility: Vaccine Supply chain officer, stock management officer, Cold chain senior officer, vaccine distributor and cold chain officer.

Review the monthly reports and check the following:

a. The stock level for each product is between its maximum stock and safety stock level.
b. Products with short expiry dates are distributed in a manner that ensures, wherever possible, that they will be used before the expiry date is reached.

Reasons:

- To ensure that programme managers are fully informed about the current stock position.
- To ensure that programme managers are able to adjust the delivery timetable for future supplies to avoid stockouts or over-stocking.

24.5 Every three months

Responsibility: Vaccine stock management officer, Cold chain officer, vaccine supply chain officer, vaccine distributor

a. Carry out a physical stock count of all vaccines, diluents and immunization supplies. See EVM-SOP-E6-03: *Conducting a physical stock count*.
b. Adjust the stock records as necessary to match the stock count. Record the reasons for the adjustment in the stock control system. Refer to the software User Guide.
c. Submit a stock adjustment report to cold chain senior office showing the physical count for each product next to the figure recorded in the stock control system.

Responsibility: Cold chain senior officer and vaccine supply chain officer, vaccine distributor, vaccine stock management officer

a. Check the stock adjustment report.
b. If the physical stock count for each item is greater than ±1% of the figure recorded in the stock control system, investigate the reason for the discrepancy.

Reason: To verify that stock records are correct and record and assess the reason for any adjustments and discrepancies.

24.6 Vaccine losses caused by expiry or damage

Responsibility:

Vaccine stock management officer, Vaccine supply chain officer, vaccine distributor

Follow the procedures set out in EVM-SOP-E6-04: *Safe disposal of expired or damaged vaccine and diluents.* Record the losses in the stock control system.

24.7 Every year on 05 January

Responsibility: Vaccine supply chain officer and the IT personnel

a. Check for software updates. If there is a new version, obtain a copy of the CD and install the update.
b. At least one month before the expiry of the current subscription, check that the annual subscription for the anti-virus software has been paid and that all updates have been installed.
c. Create an archive file on CD and store it in a safe place.

24.8 Every year

Responsibility: Vaccine supply chain officer and IT personnel.

a. Create an Archive file as described in the software User Guide.
b. Backup the archive on a external hard disk, label it as a stock control archive and store it in a safe place.

Reason:

- To reduce the size of the database file.
- To remove data on supplies that have been consumed and are no longer in the supply chain.
- To ensure that these data are still available in case there is an AEFI that needs to be investigated.

25. Related documents and SOPs

- EVM-SOP-E6-03: *Conducting a physical stock count*
- EVM-SOP-E6-04: *Safe disposal of expired or damaged vaccine and diluents*
- <Stock control software user guide>

	Standard Operating Procedure **Managing diluents in the supply chain**		
Approvals	**Name**	**Date**	**Signature**
Authorized by:	Ministry of Health		
Reviewed by:	Rwanda, UNICEF CO	May 2016	
Revised by:	Vaccine Preventable Disease Program	October 2015	
Original author:	WHO		

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1	07 Oct 2011	Original	
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Table of content

Distribution

Distribute this SOP to the following:

Facility type	Position(s)

Standard Operating Procedure

Managing diluents in the supply chain

26. Policy and objectives

26.1 Policy

Responsible personnel should know that all vaccines and diluents have an expiry date, after which they must not be used. Vaccine manufacturers formulate diluents to suit the needs of their own vaccines. They are not interchangeable with diluents supplied by other manufacturers, even if the type of vaccine is the same. Diluents may appear to be plain water-for-injection but they usually contain additives.

Responsible personnel should understand that freeze-dried vaccines must always be issued with the correct diluents in matching quantities. Health workers should know that freeze-dried vaccines must always be reconstituted using the specific diluent provided by the manufacturer for each type and batch of vaccine, and that both vaccine and diluent must be within their labelled expiry dates.

26.2 Objectives

This SOP describes how diluent stocks should be managed throughout the supply chain so that vaccine and diluent stocks always match one another closely[10] and health workers are always able to reconstitute freeze-dried vaccine with the correct diluent.

27. Responsibility

All personnel who have responsibility for vaccines and diluents in vaccine stores, health facilities, and during transport:

1. CVS: Vaccine stock management officer, Vaccine supply chain officer
2. DISTRICT LEVEL: Vaccination program focal point and M&E
3. HEALTH CENTER: Incharge of vaccination and head of HC

28. Associated materials and equipment

Packing materials.

29. Procedure

29.1 Record diluent arrivals in the stock records

Responsibility:

CVS: Vaccine stock management officer, Vaccine supply chain officer

DISTRICT LEVEL: Vaccination program focal point and M&E

HEALTH CENTER: Incharge of vaccination and head of HC

[10] Some discrepancies will occur because vaccine manufacturers typically over-supply diluents to compensate for the risk of breakage. Consequently, there should never be a reason for under-supplying diluent to any store or health facility.

All stores must record the following minimum information for vaccine diluents when they are received in the store from the vaccine manufacturer or from a higher level storage facility:

a. Type of vaccine for which the diluent is intended.

b. Manufacturer of the diluent.

c. Vial presentation (doses per vial).

d. Batch number(s).

e. Expiry date.

f. Number of doses received.

29.2 Record outgoing diluent in the dispatch records

Responsibility:

4. CVS: Vaccine stock management officer, Vaccine supply chain officer

5. DISTRICT LEVEL: Vaccination program focal point and M&E

6. HEALTH CENTER: Incharge of vaccination and head of HC

All stores must record the following minimum information for vaccine diluents when they are dispatched by the store to a lower level facility:

a. Type of vaccine for which the diluent is intended.

b. Manufacturer of the diluent.

c. Vial presentation (doses per vial).

d. Batch number(s).

e. Expiry date.

f. Number of doses issued.

29.3 Issue diluents correctly

Responsibility:

CVS: Vaccine stock management officer, Vaccine supply chain officer

DISTRICT LEVEL: Vaccination program focal point and M&E

HEALTH CENTER: Incharge of vaccination and head of HC

All outgoing freeze-dried vaccines must be accompanied by diluents which meet the following requirements:

a. The correct diluent (same manufacturer, same vaccine type and same vial/ampoule size).

b. The number of diluent vials issued must exactly match the number of vaccine vials, even if the lower level store or health facility reports unequal quantities of vaccine and diluent in its requisition form[11].

c. Compatible expiry date to the vaccine[12].

[11] Failure to observe this rule means that lower levels stores and health facilities will have increasingly unbalanced stocks of vaccine and diluent. Attempts to adjust for this will cause shortages of diluent and/or vaccine.

Pack and transport diluents correctly

Responsibility:

7. CVS: Vaccine stock management officer, Vaccine supply chain officer
8. DISTRICT LEVEL: Vaccination program focal point and M&E
9. HEALTH CENTER: Incharge of vaccination and head of HC

Diluent ampoules are fragile. The lightweight inner cartons must be packed in outer cartons with sufficient padding material to prevent movement. Diluents must not be exposed to temperatures below 0°C during transport.

29.4 Store diluents correctly at Central Vaccine Store and district stores

Responsibility: Supply chain officer

10. CVS: Vaccine stock management officer, Vaccine supply chain officer
11. DISTRICT LEVEL: Vaccination program focal point and M&E

a. Diluents which are supplied already packed with the vaccine must be kept in the cold chain at +2°C to +8°C[13].

b. Diluents which are supplied separately from the vaccine must be stored in a clearly marked area of the store, arranged by vaccine type, vaccine manufacturer and date of expiry.

c. Diluent which are supplied separately from the vaccine must be protected from physical damage, moisture, excessive heat and temperatures below 0°C[14].

29.5 Store diluents correctly at health centre and service delivery level

Responsibility: <Incharge of vaccination program.

At health center level, and during outreach sessions, all diluents must be stored in the cold chain at +2°C to +8°C.

30. Related documents and SOPs

EVM-SOP-E6-01: *Using computerized stock*

[12] The diluent may not have the same expiry date as the vaccine. It may be shorter or longer. If it is shorter, then the expiry date of the diluent will determine the last date on which the vaccine can be used.

[13] For example, DTP-HepB+Hib vaccine comes as a two vial combination with DTP-HepB as the 'diluent' and Hib as the freeze-dried component.

[14] If diluents are frozen, the ampoules are likely to break.

	Standard Operating Procedure **Storing vaccine and water packs in refrigerators and freezers**		
Approvals	**Name**	**Date**	**Signature**
Authorized by:	Ministry of Health		
Reviewed by:	Rwanda, UNICEF CO	May 2016	
Revised by:	Vaccine Preventable Disease Program	October 2015	
Original author:	WHO		

Version history

No	Date	Description of change	Reason for change
1	07 Oct 2011	Original	
2	16 May 2016	Edited to Context of Rwanda	
3			
4			
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Standard Operating Procedure

Storing vaccine and water packs in refrigerators and freezers

31. Policy and objectives

31.1 Policy

Responsible personnel must know how to store vaccine and water packs correctly in refrigerators and freezers. Correct storage practice ensures that:

a. All vaccines are clearly identifiable and accessible and can easily be located and distributed in Earliest-Expiry-First-Out (EEFO) order.
b. Freeze-sensitive vaccines are stored in areas where there is no risk of freezing.
c. Cold air can flow freely around the stock.
d. Vaccine marked for disposal is kept separate from the remaining stock and should be out of refrigerator.

31.2 Objectives

This SOP describes how to store vaccine in refrigerators and freezers.

32. Responsibility

Vaccination program focal point at district level and in charge of vaccination at HC has responsibility for vaccine storage. M&E at district hospital level and Head of HC at HC level have supervisory duties.

33. Associated materials and equipment

None

34. Procedure

Store all vaccines at the correct temperature.

Refer to EVM-SOP-E2-03: *Correct storage temperatures for vaccines and diluents.*

34.1 General procedures

Responsibility: Vaccination program focal point at district level and in charge of vaccination at HC have

Arrange stock: Arrange vaccines and diluents (where diluents are stored in refrigerators) by type, batch number and expiry date so that they can be accessed in Earliest-Expiry-First-Out (EEFO) order.

a. *District Hospital store*: If there is more than one vaccine refrigerator and/or vaccine freezer:

- Try to store one type of vaccine only in each refrigerator.
- Print a contents list and attach it to the lid or door of the appliance. The list must show vaccine type, manufacturer, presentation, batch number and expiry date. Replace the list with an updated version whenever vaccine is removed from stock or additional vaccine is added.
- DO NOT store diluents in the refrigerator.

b. *In health Centre and all service delivery refrigerators*:

- Store vaccine AND diluents in the refrigerator. If there is insufficient space, for all the diluent make sure you keep enough diluent in the refrigerator for the next immunization session.
- DO NOT store expired vaccines, reconstituted vials with doses remaining after an immunization session, and vials with VVMs that have reached or are beyond their discard point.
- Keep vials with VVMs showing more heat exposure than others in the box labelled 'use first'. Use these vials first in the next session.
- Keep opened vials of OPV, TT HepB and Pentavalent vaccines, marked with the date of opening and place in the 'USE FIRST' box for first use during the next session.

c. *Cooling and freezing water packs:*

- DO NOT use a refrigerator that contains vaccine to prepare cool water packs if extra refrigerator is available. In all other cases, use same separate refrigerator.
- DO NOT freeze water packs in a freezer that contains vaccine unless the appliance has a separate ice pack freezing compartment.
- Try to store unfrozen water packs upright to reduce the risk of leakage. Frozen water packs may be stored flat.
- *Hygiene:* ALWAYS wash hands thoroughly before handling vaccine cartons and vaccine vials.

34.2 Storing vaccine and water packs in ice-lined refrigerators

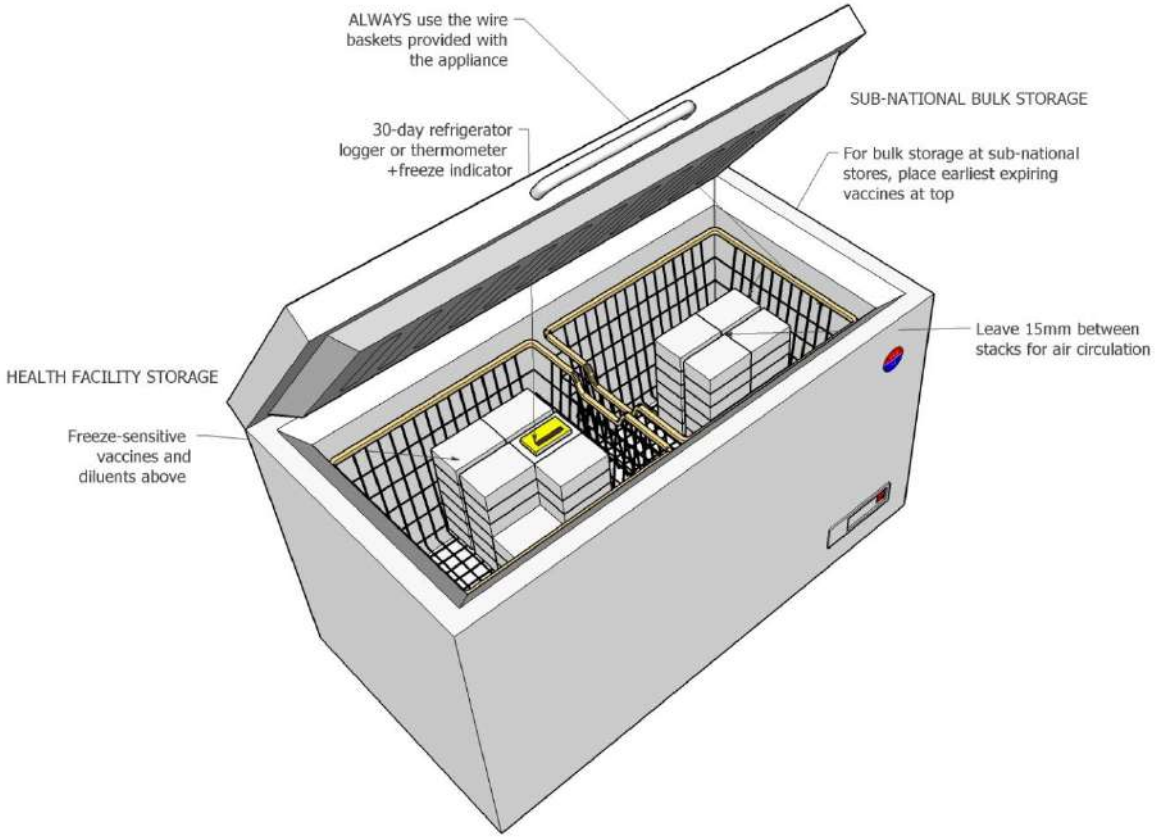
Responsibility: Vaccination program focal point at district level and incharge of vaccination at HC

1. Place vaccine and diluent cartons (where diluents are stored in the refrigerator) in the wire baskets provided with the refrigerator. NEVER remove the baskets to create additional storage space. Leave a vertical space between stacks of cartons to allow air to circulate
2. Place the thermometer and freeze indicator device or 60-day electronic temperature data logger[15] on the top of the stock, with the freeze-sensitive vaccines, so that it can easily be read.
3. If there is a separate freezing compartment, use this to freeze water packs. DO NOT exceed the maximum number and weight of water packs stated in the refrigerator manufacturer's instructions.
4. NEVER cool water packs in a refrigerator that contains vaccine. ALWAYS use a separate refrigerator that has been designated for this purpose if available.

[15] For suitable devices, refer to section E006 in the PQS catalogue on the WHO website.

5. Arrange vaccines and diluents as shown in the diagram below. The left hand side shows an arrangement with mixed vaccine stored at health facility level. The right hand side shows an arrangement for bulk vaccine storage at district level. Note that older ILRs with adjustable thermostats may experience low temperatures if the thermostat is not correctly adjusted. Correct adjustment is critical. Placing a layer of unfrozen water packs at the bottom of the unit also helps to reduce the risk of freezing in such units.

6. **Storing vaccine in an ice-lined refrigerator**



Source: WHO/EPELA (adapted)

34.3 Storing vaccines and water packs in top opening refrigerators

Responsibility: Vaccination program focal point at district level and in charge of vaccination at HC

a. Place the thermometer and freeze indicator device or 60-day electronic temperature data logger[16] on the top of the stock, with the freeze-sensitive vaccines, so that it can easily be read.

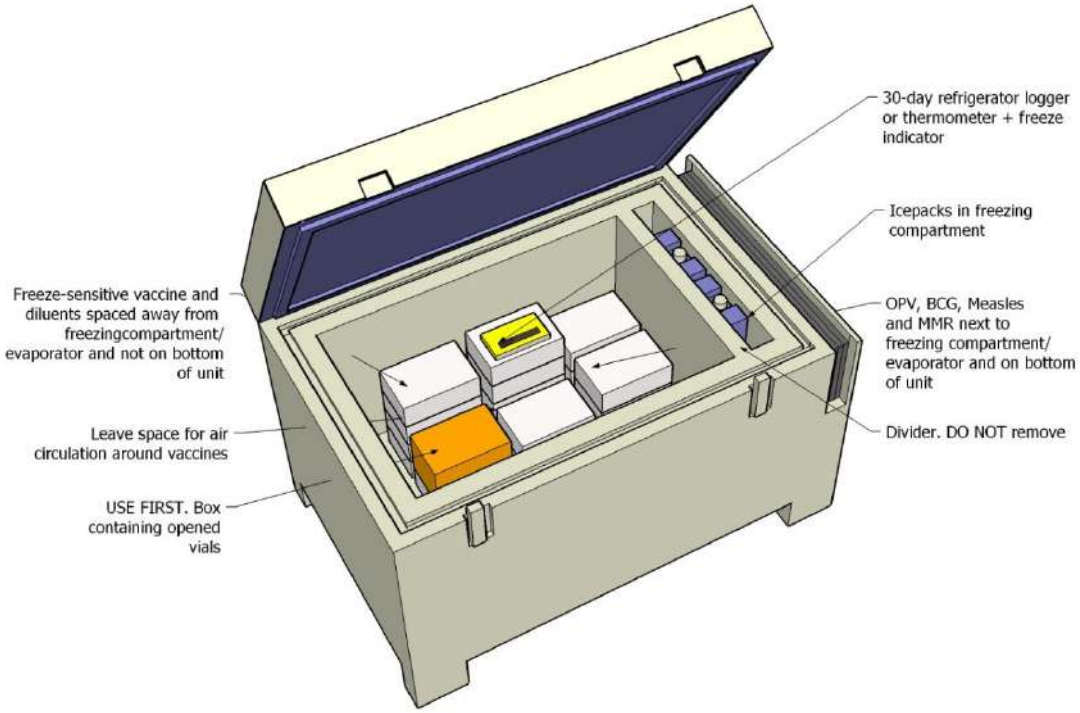
b. If there is a separate freezing compartment, use this to freeze water packs. DO NOT exceed the maximum number and weight of water packs stated in the manufacturer's instructions.

[16] For suitable devices, refer to section E006 in the PQS catalogue on the WHO website.

c. NEVER cool water packs in a refrigerator that contains vaccine. ALWAYS use a separate refrigerator that has been designated for this purpose if extra refrigerator is available.

d. Arrange vaccines and diluents as shown in the diagram below.

Storing vaccine in a top opening health centre refrigerator



Note: This drawing applies typically to gas and kerosene refrigerators of the RCW type, and to similar products.

34.4 Storing vaccine and water packs in front-opening refrigerators

Responsibility: Vaccination program focal point at district level and in charge of vaccination at HC

a. Place the thermometer and freeze indicator device or 60-day electronic temperature data logger[17] with the freeze-sensitive vaccines on the middle shelf.

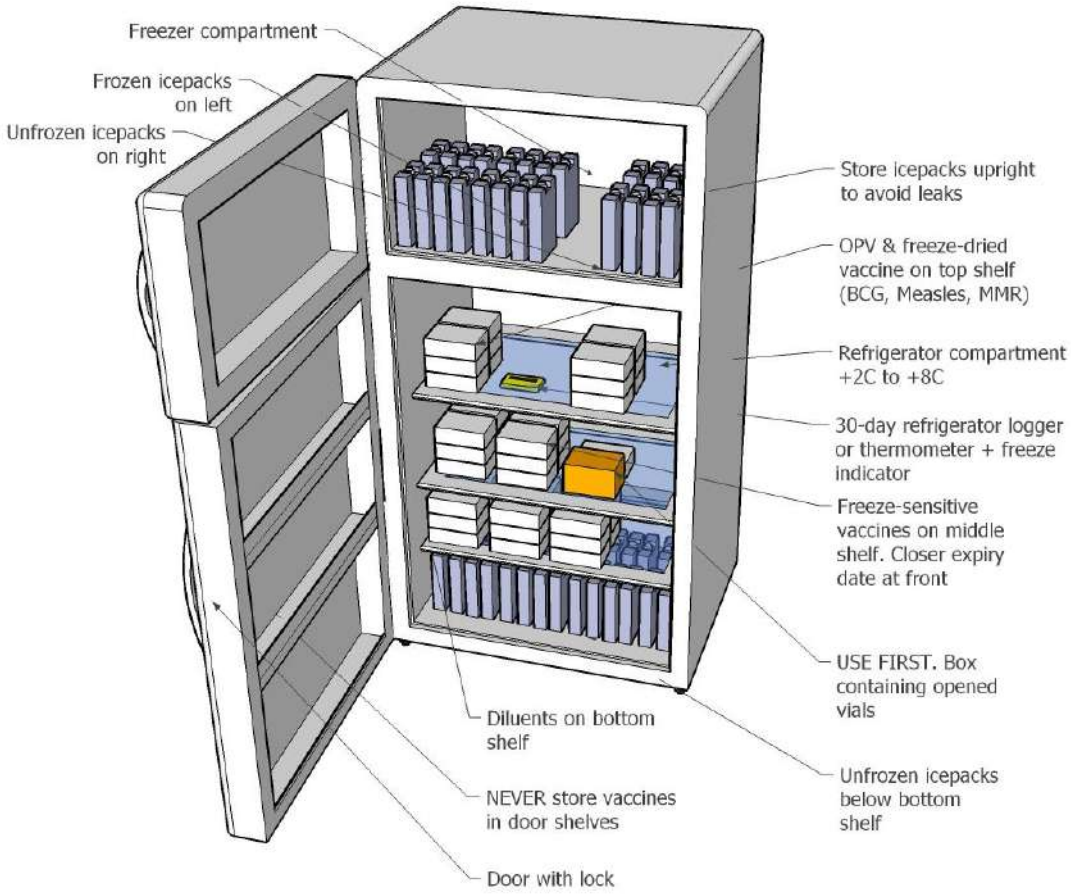
b. If there is a separate freezing compartment, use this to freeze water packs. DO NOT exceed the maximum number and weight of water packs stated in the manufacturer's instructions.

c. NEVER cool water packs in a refrigerator that contains vaccine. ALWAYS use a separate refrigerator that has been designated for this purpose if extra refrigerator is available.

d. Arrange vaccines, diluents and water packs as shown in the diagram below.

[17] For suitable devices, refer to section E006 in the PQS catalogue on the WHO website.

Storing vaccine in front-opening refrigerator



Note: This applies typically to gas and kerosene front opening refrigerators and to domestic refrigerators.

34.5 Storing vaccine in chest freezers

Responsibility: Vaccination program focal point at district level and in charge of vaccination at HC

a. Place vaccine cartons in the freezer compartment.

b. Place the thermometer on the top of the cartons so that it is easily accessible.

c. NEVER freeze water packs in a freezer that contains vaccine. ALWAYS use a separate freezer that has been designated for this purpose if extra refrigerator is available.

d. NEVER store diluent in a freezer.

34.6 Freezing and storing water packs

Responsibility: Vaccination program focal point at district level and in charge of vaccination at HC

a. *Upright ice pack fast freezers:* Stack water packs on the shelves and wait for them to freeze. Once they are frozen they can either be kept in the fast freezer or moved to a chest freezer for storage purposes.

b. *Chest freezers with separate freezing compartment:* If the freezer has a separate freezing compartment, use this to freeze ice packs. If there is a fast freeze switch, activate the switch. Once the packs are frozen, move them to the storage compartment and freeze a further batch of water packs in the freezing compartment.

c. *Chest freezers with a single compartment:* Place unfrozen water packs evenly around the inner walls of the appliance. Once the packs are frozen, lay them on the bottom of the compartment and freeze a further batch.

35. Related documents and SOPs

- EVM-SOP-E2-03: *Correct storage temperatures for vaccines and diluents.*
- EVM-SOP-E5-03: *Looking after vaccine refrigerators and freezers.*
- EVM-SOP-E6-03: *Conducting a physical stock count.*
- EVM-SOP-E6-04: *Safe disposal of expired or damaged vaccine and diluents.*
- EVM-SOP-E6-05: *Storing vaccines and water packs in cold rooms and freezer rooms.*
- EVM-SOP-E7-03: *Packing vaccine and diluents for transport, using cold boxes.*

	Standard Operating Procedure **Conditioning frozen icepacks**		
Approvals	**Name**	**Date**	**Signature**
Authorized by:	Ministry of Health		
Reviewed by:	Rwanda, UNICEF CO	May 2016	
Revised by:	Vaccine Preventable Disease Program	October 2015	
Original author:	WHO		

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Distribution

Distribute this SOP to the following:

Facility type	Position(s)
CVS	Vaccine stock management officer, vaccine distributor
DHL	EPI supervisor
HC	Vaccinator, vaccination focal point

36. Policy and objectives

36.1 Policy

Responsible personnel should know how to pack vaccine for transport and should understand the importance of keeping vaccines at the correct temperature throughout the journey. When frozen icepacks are used to line cold boxes or vaccine carriers that contain freeze-sensitive vaccines, they must always be 'conditioned' beforehand to minimize the risk of damage to the vaccine.

36.2 Objectives

This SOP describes how icepack conditioning should be carried out and when conditioned icepacks should be used. It includes a learning guide for training purposes.

37. Responsibility

Vaccine stock management officer, vaccine distributor, vaccine supply chain officer, senior cold chain officer and Health Workers responsible for packing vaccine.

38. Associated materials and equipment

Conditioned icepacks. Large table or other work surface on which to lay out the icepacks.

39. Procedure

39.1 What is a conditioned icepack?

When an icepack is removed from the icepack freezer, its temperature may be as low as -20°C. If you use these icepacks immediately there is a risk that you will damage freeze-sensitive vaccines.

A 'conditioned' icepack is an icepack that has been left outside the freezer for long enough to stabilize at 0°C. This point is reached when the ice inside the icepack begins to melt.

39.2 How do I know when an icepack is conditioned?

An icepack is conditioned as soon as the ice core inside the pack is surrounded by a small amount of liquid water. You can check this by shaking the icepack. If you can feel the ice moving inside the pack, it is fully conditioned. This process takes time – up to 30 minutes or more, depending upon the temperature of the room.

39.3 When to use conditioned icepacks

Note: OPV which should always be transported with fully frozen or conditioned icepacks, except in the case of outreach sessions.

Conditioned icepacks must ALWAYS be used whenever you pack the following freeze-sensitive vaccines in a cold box or vaccine carrier:

List of freeze sensitive vaccines in the program.

1. DTP-HepB-Hib

2.

You must also use conditioned icepacks whenever you pack a load of vaccines which contains freeze-sensitive products mixed together with:

- List non freeze sensitive vaccines in your schedule, e.g.: BCG, OPV, MMR

You DO NOT need to use conditioned icepacks when you are packing OPV on its own.

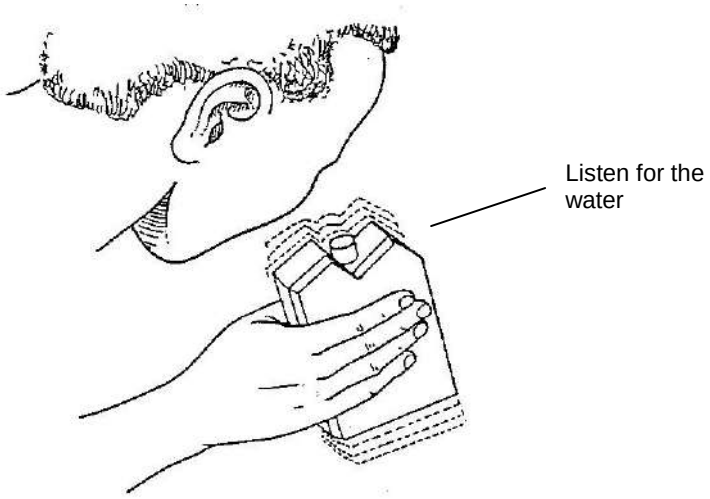
39.4 How to condition icepacks

a. Calculate how many icepacks are needed for the vaccine consignment. The underside of the lid of the cold box or vaccine carrier usually has a diagram showing the number required for that type of box or carrier.

b. Remove the correct number of icepacks from the freezer.

c. Lay the icepacks on the designated table or works surface in a single layer leaving a 5 cm space all round each pack.

d. Check progress every 10 minutes by shaking a sample of icepacks as shown below.



e. Wait until ALL the icepacks are conditioned; then use them to line the cold boxes and/or vaccine carriers. Pack the vaccine.

39.5 Training

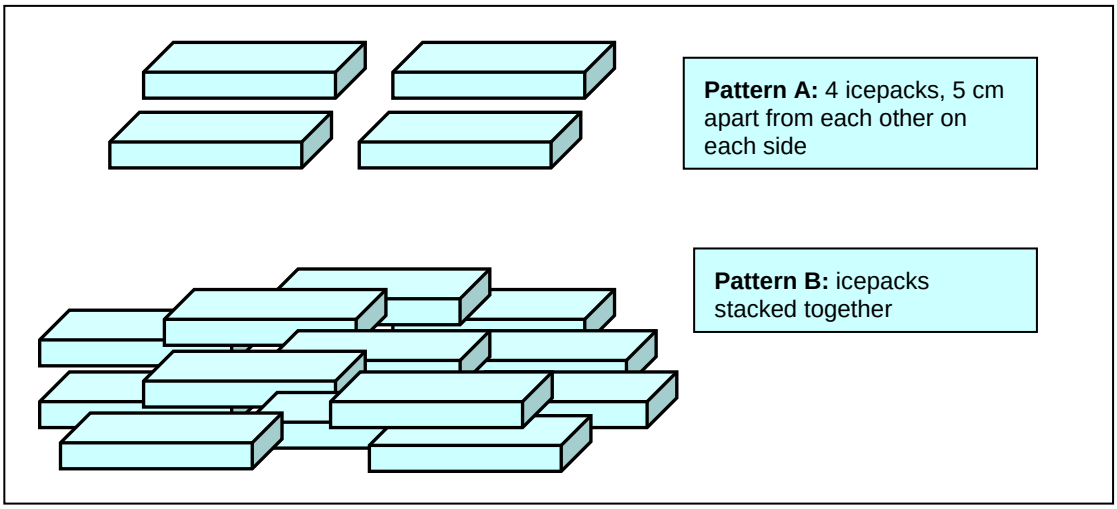
Conduct training based on this SOP using the *Icepack conditioning learning guide* in Annex 1. This training must be given to all personnel whose duties require them to pack vaccines in cold boxes or vaccine carriers.

40. Related documents and SOPs

- EVM-SOP-E7-02: *Packing vaccine and diluents for transport using cold boxes*
- EVM-SOP-E7-03: *Packing vaccine and diluents in vaccine carriers.*

Annex 1 – Icepack conditioning learning guide

1. Prepare frozen icepacks a day before the training. Make sure that you have minimum of one icepack for each participant. Store them in a cold box immediately you remove them from the freezer.
2. Explain what a 'conditioned' icepack is.
3. Explain which vaccines must be packed with conditioned icepacks.
4. Distribute one icepack to each participant.
5. Ask each participant to mark one of the icepacks with a sign that they can recognize, using a permanent marker pen.



6. Ask participants to place the icepacks on the table top as shown in the diagram above.
7. Twice, during the course of the session, ask the participants to go and check their icepacks. The second check should only be carried when all the icepacks in the **Pattern A** arrangement are fully conditioned. The trainer should check that conditioning is complete before inviting the participants to check for themselves.
8. Make sure that every participant handles a fully conditioned icepack and understands that there must always be some liquid water inside the pack.
9. When the exercise is over, explain to participants that conditioning takes time and requires patience and that the time required depends upon room temperature.
10. Make sure that all participants fully understand the process and know which vaccines must always be packed with conditioned icepacks.

	Standard Operating Procedure **When and how to conduct the Shake Test**

Approvals	**Name**	**Date**	**Signature**
Authorized by:	Ministry of Health		
Reviewed by:	Rwanda, UNICEF CO	May 2016	
Revised by:	Vaccine Preventable Disease Program	October 2015	
Original author:	WHO		

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Distribution

Distribute this SOP to the following:

Facility type	Position(s)
CVS	Vaccine stock management officer, vaccine distributor, senior cold chain officer
DHL	EPI supervisor
HC	Vaccinator, vaccination focal point

Standard Operating Procedure

When and how to conduct the Shake Test

41. Policy and objectives

41.1 Policy

The Shake Test is designed to determine whether aluminium adsorbed vaccines have been frozen. Whenever it is suspected that vaccine has been frozen, at least one member of the duty personnel in every facility that stores vaccine should know how to perform and interpret the test reliably and correctly. Vaccine which fails the Shake Test should not be distributed or administered.

41.2 Objectives

This SOP explains when to do the Shake Test and what to do if you find vaccine that has been damaged by freezing. The Shake Test protocol is attached as Annex 1 and **must not be altered** – there is only one correct way to conduct this test.

42. Responsibility

All personnel who have responsibility for looking after vaccine and for checking its condition: Logistics team, Vaccination supervisors, vaccinators.

43. Associated materials and equipment

Access to a refrigerator with freezing compartment, or a freezer is essential. The test cannot be carried out in facilities that are only equipped with a refrigerator without a freezing compartment.

44. Procedure

44.1 Training

All staff responsible for looking after vaccine must be trained to conduct the Shake Test correctly.

44.2 Applicability

The Shake Test currently applies to the following vaccines:

- DTP-HepB-Hib liquid
- Hepatitis B
- HPV
- Pneumococcal
- TT

Note: Rotavirus vaccine is a liquid vaccine, prone to freezing. If suspected to be frozen, the Shake test is not done, the vaccine shouldn't be used at all.

After freezing, the bonds between the aluminium adsorbent and the antigen in a vaccine are broken. Separated adsorbent tends to form larger, heavier granules that gradually settle at the bottom of the vial when this is shaken. Sedimentation occurs

faster in a vaccine vial which has been frozen than in a vaccine vial from the same manufacturer which has never been frozen.

When carried out correctly the Shake Test has been shown to have 100% sensitivity and 100% specificity and 100% positive predictive value[18].

44.3 When and how to do a Shake Test

If a freeze indicator or other temperature monitoring device shows a freeze alarm, or if you suspect that freezing has occurred, then the shake test must be done to confirm the status of the vaccine. Follow the Shake Test Protocol exactly as described in **Annex 1**.

Individual batches of vaccine may behave differently from one another. Therefore, the procedure should be repeated with *all* suspect batches. Follow the appropriate sampling methodology as set out in Section 4.4 to ensure that all of the damaged vaccine is identified and that none of this damaged vaccine is distributed or used.

The Shake Test need NOT be conducted under the following circumstances:

- When solid frozen vaccine vial(s) have been found.

44.4 Sampling methodologies

The method for selecting the *test sample* depends upon two factors:

1. The number of vials you suspect have been frozen.

2. Whether the vaccine has been accepted from the vaccine supplier and has entered the country supply chain.

44.4.1 Sampling incoming shipments from the vaccine supplier

When vaccine arrives from the vaccine supplier it must be inspected and approved before it can be accepted into the country supply chain. International shipments arranged by UNICEF Supply Division will always have an electronic shipping indicator in each and every shipping container. Proceed as follows:

a. Mark and isolate any shipping container(s) where the electronic shipping indicator shows a freeze alarm. Keep the shipping containers in the cold chain.

b. Inspect each suspect container individually following the sampling procedure described in **Annex 1.** Draw the correct number of sample vials from locations throughout the suspect container(s), including the middle of the container(s). Remember to prepare a frozen control sample for each individual vaccine batch.

c. Send the shake test results to the vaccine supplier. In the case of UNICEF-procured or donated vaccine, supply the shake test results to UNICEF or to the donor for a final decision on what to do with the consignment.

d. If the decision is taken to dispose of the vaccine, discard all vaccine in the affected container(s).

[18] Kartoğlu, Ü, *et al. Validation of the shake test for detecting freeze damage to adsorbed vaccines.* Bulletin of the World Health Organization, 2010; 88:624-631 http://www.who.int/bulletin/volumes/88/8/08-056879/en

44.4.2 Sampling vaccine that is already in the supply chain

a. *Small numbers, single batch:* If there are only a small number of vials to be tested, and these are all from the same batch, then you should test all the vials against the control sample. A typical example would be a single refrigerator or cold box where freezing is suspected. In this case, discard all vials that fail the test and keep those which pass the test.

b. *Small numbers, more than one batch:* If there are a small number of vials to be tested, but there is more than one batch or more than one type of freeze-sensitive vaccine, then you will need to repeat the shake test for each batch and for each vaccine. In this case, discard all vials that fail the test and keep those which pass the test. **Remember:** you must also prepare a frozen control sample for each batch and for each vaccine.

c. *Large numbers:* If there are a large number of suspect vials, for example, in a cold room or a large refrigerator, you should follow the sampling procedure described in MIL-STD-105E or, a similar sampling standard, inorder to establish the extent of the problem. See **Annex 2.** Draw the correct number of sample vials from locations evenly distributed throughout the suspect load. If any vials in the sample fail the Shake Test, all the suspect vials must be discarded, including those that have not been tested.

44.5 Disposal of freeze-damaged vaccine and frozen control samples

After you have completed the test(s) described above, discard all freeze-damaged vials and all control samples as described in EVM-SOP-E6-04: *Safe disposal of damaged or expired vaccine*.

You should never issue a vaccine vial that has deliberately been frozen as a *control sample* for a Shake Test; these vials must always be kept separated from the general stock. There are two cases to consider.

CASE 1: You may want to keep the control sample and use it for further tests. This only applies while you still hold stocks of the same batch of the same vaccine.

CASE 2: If the control sample batch has all been issued, the sample must be set aside for final disposal.

Proceed as follows:

a. Use the stock control system to 'issue' the control sample(s) for the shake test. This ensures that the vials are properly accounted for.

b. *If the control sample is to be kept for further tests*: Place the control sample in a closed plastic container in a cold room or vaccine refrigerator, clearly marked: 'CURRENT SHAKE TEST CONTROL SAMPLES'.

c. *If the control sample batch has all been issued:* Place the control sample in a closed plastic container outside the cold room, clearly marked: 'SHAKE TEST CONTROL SAMPLES FOR DISPOSAL– DO NOT USE''.

45. Related documents and SOPs

- EVM-SOP-E6-04: *Safe disposal of damaged or expired vaccine.*
- *Military Standard: sampling procedures and tables for inspection by attributes*MIL-STD-105E

Annex 1: Shake test protocol

<table>
<tr><td colspan="2">NOTES:
1) This protocol must not be altered. There is only one correct way to conduct a Shake Test.
2) The test procedure described below should be repeated with all suspect batches. In the case of international arrivals, the shake test should be conducted on a random sample of vaccine. However, if there is more than one lot in the shipment, the random sample must include a vial taken from each and every lot.</td></tr>
<tr><td colspan="2">1. Take a vial of vaccine of the same type and batch number as the vaccine you want to test, and made by the same manufacturer.</td></tr>
<tr><td colspan="2">2. Clearly mark the vial as “FROZEN.”</td></tr>
<tr><td colspan="2">3. Freeze the vial in a freezer or the freezing compartment of a refrigerator until the contents are completely solid.</td></tr>
<tr><td colspan="2">4. Let it thaw. Do <u>NOT</u> heat it!</td></tr>
<tr><td colspan="2">5. Take your “TEST” vial from the batch that you suspect has been frozen.</td></tr>
<tr><td colspan="2">6. Hold the “FROZEN” vial and the “TEST” vial together in one hand.</td></tr>
<tr><td colspan="2">7. Shake both vials vigorously for 10-15 seconds.</td></tr>
<tr><td colspan="2">8. Place both vials on a flat surface side-by-side and start continuous observation of the vials until test is finished.
(NOTE: If the vials have large labels, which conceal the vial contents, turn both vials upside down and observe sedimentation in the neck of the vial.)</td></tr>
<tr><td colspan="2">Use an adequate source of light to compare the sedimentation rates between vials.
IF,</td></tr>
<tr><td>9. The TEST vial sediments slower than the FROZEN vial,
THEN,</td><td>10. Sedimentation is similar in both vials
OR
The TEST vial sediments faster than the FROZEN vial
THEN,</td></tr>
<tr><td>11. Use the vaccine batch.</td><td>11. <u>Vaccine damaged</u>: Notify your supervisor. Set aside all affected vaccine in a container marked “DAMAGED VACCINE FOR DISPOSAL– DO NOT USE’’</td></tr>
<tr><td rowspan="2"></td><td>12. Discard all affected vaccine once you have received permission to do so.</td></tr>
<tr><td>13. Fill in the Loss/Adjustment Form.</td></tr>
</table>

Annex 2: Sampling method

Any pharmaceutical system should have a quality control plan in place which describes the sampling procedure to be used in cases such as the one given in the example below.

This annex shows how to use a quality control sampling system such as MIL-STD-105D or E[19].This USA military standard has been used for many years as a sampling procedure. Other similar systems are also described by ANSI and ISO.

Example:

A batch of Hepatitis B Vaccine is held at the central store. The temperature records show that the vaccine may have been frozen during storage.

The batch consists of 15,000 vials. It is impossible to do the shake test on all the vials and a representative sample must therefore be tested. How many vials should be tested in order to indicate the status of the batch?

Notes on sampling:

1. It is assumed that a 'normal' inspection level will be adequate.

2. For freeze sensitive vaccines, freezing is a *critical defect* and therefore the acceptance/rejection criteria will always be 0 and 1. This means that you can accept the shipment if zero vials in the sample fail the test, but you **must** reject the shipment if one or more vials in the sample fails.

[19]MIL-STD-105D has been superseded by MIL-STD-105E which in turn has been superseded by MIL-STD-1916.

Step 1: Refer to Table 1 on page 13 of the Standard. Find the appropriate size range for the shipment in the *Lot or batch size* column as shown in the example below.

Step 2: Find the matching sample size code in the *General Inspection Levels* column II as shown in the example.

TABLE I — Sample size code letters

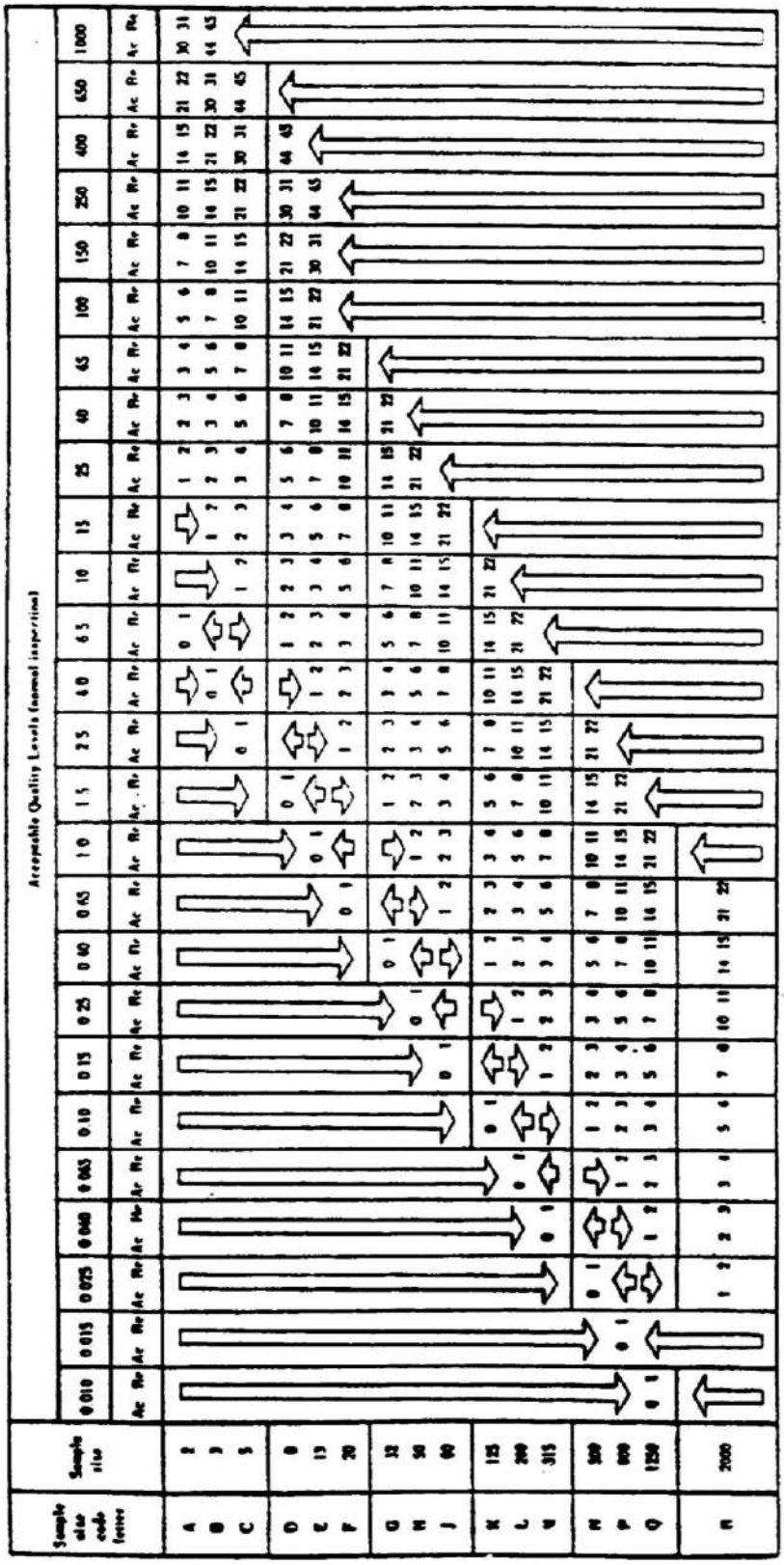
(See 4.9.1 and 4.9.2)

Lot or batch size	Special inspection levels					General inspection levels		
	S-1	S-2	S-3	S-4	I	II	III
2 to 8	A	A	A	A	A	A	B
9 to 15	A	A	A	A	A	B	C
16 to 25	A	A	B	B	B	C	D
26 to 50	A	B	B	C	C	D	E
51 to 90	B	B	C	C	C	E	F
91 to 150	B	B	C	D	D	F	G
151 to 280	B	C	D	E	E	G	H
281 to 500	B	C	D	E	F	H	J
501 to 1200	C	C	E	F	G	J	K
1201 to 3200	C	D	E	G	H	K	L
3201 to 10000	C	D	F	G	J	L	M
10001 to 35000	C	D	F	H	K	M	N
35001 to 150000	D	E	G	J	L	N	P
150001 to 500000	D	E	G	J	M	P	Q
500001 and over	D	E	H	K	N	Q	R

MIL-STD-105E

TABLE II-A—Single sampling plans for normal inspection (Master table)

(see 4.9.3 and 4.9.4)



	Standard Operating Procedure **Using Vaccine Vial Monitors**		
Approvals	**Name**	**Date**	**Signature**
Authorized by:	Ministry of Health		
Reviewed by:	Rwanda, UNICEF CO	May 2016	
Revised by:	Vaccine Preventable Disease Program	October 2015	
Original author:	WHO		

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Distribution

Distribute this SOP to the following:

Facility type	Position(s)

Standard Operating Procedure

Using Vaccine Vial Monitors

46. Policy and objectives

46.1 Policy

WHO requires that all WHO pre-qualified vaccines are supplied with the appropriate Vaccine Vial Monitor (VVM) applied to the vaccine vial or ampoule. Countries that order vaccine through a UN procurement agency such as UNICEF Supply Division will receive vaccines supplied with VVMs.

46.2 Objectives

Storekeepers and health workers who are responsible for handling vaccines at all levels of the supply chain must know how to read, interpret VVM colour changes and how to act correctly when a colour change is observed.

47. Responsibility

All personnel who have responsibility for looking after vaccine and for checking its condition.

48. Associated materials and equipment

VVM poster.

49. Procedure

49.1 Training

Conduct training based on this SOP for all personnel responsible for managing or administering vaccines – see Annex 1.

49.2 Using VVMs

VVM status should be checked at the following times:

49.2.1 When vaccines are received at the central level store

Location: Central level store

Responsibility: Stock management officer Check VVM status and complete the Vaccine Arrival Report as described in EVM-SOP-E1-02: *Vaccine arrival procedures.*

49.2.2 When vaccines are issued by a store

Location: All stores which issue vaccine to lower level stores

Responsibility: Storekeeper

a. Check VVM status and expiry dates for each type and batch of vaccine during preparation of the issue voucher. Generally make sure that any vaccine which shows the most VVM exposure is issued first[20].

b. Record VVM status for each vaccine and each batch on the issue voucher.

49.2.3 When vaccines are received by a lower level store

Location: District hospital and health centres stores

Responsibility: Storekeeper, EPI Supervisor and incharge of vaccination at Health centre

a. Check a sample of each batch of each vaccine received. Record VVM status on the arrival voucher. Compare the observed VVM status with the VVM status recorded on the issue voucher and report any differences to the supplying store.

b. Ensure that vaccine which shows the most VVM exposure is clearly identified so that it can be issued as soon as possible to lower level stores or health facilities.

49.2.4 When vaccines are administered

Location: Health facility immunization session or outreach session

Responsibility: Health worker/vaccinator

a. Immediately before opening the vial, check that the VVM status is **usable** and check that the **expiry date** has not passed. If both these checks are OK, use the vaccine.

b. If the VVM status is **unusable** OR the **expiry date** has passed, DO NOT use the vaccine. Put it to one side until the end of the session and then dispose it off safely.

50. Related documents and SOPs

- EVM-SOP-E1-02: *Vaccine arrival procedures*
- EVM-SOP-E6-04: *Safe disposal of expired or damaged vaccine and diluents.*

[20] The goal is to avoid vaccine wastage during storage either due to VVM exposure or due to expiry date. You have to use your judgement here to make the correct decision.

Annex 1 – Understanding VVMs

A1.1 What is a VVM?

A VVM is a heat sensitive label which is placed on a vaccine vial to register cumulative heat exposure over time. The VVM is a circle with a small square inside it. The square contains a heat-sensitive dye.

A1.2 How does it work?

The combined effects of time and temperature cause the inner square of the VVM to darken, gradually and irreversibly:

- The lower the temperature, the more slowly the inner square changes colour.
- The higher the temperature, the faster the inner square changes colour.

A1.3 What are its limitations?

The VVM does not directly measure vaccine potency but it does give information about the main factor that affects potency: heat exposure over a period of time.

Many liquid vaccines are also damaged by exposure to freezing. The VVM does **not** register information about freezing.

A1.4 What are the VVM stages?

There are only two VVM stages. The **usable** stage is where the square is lighter than the circle. The **unusable** stage is where the square matches the colour of the circle, or is darker. The point at which the colour of the square exactly matches the colour of the circle is called the **end point.**

How to read a VVM

Usable stage

The square is lighter than the circle.
If the expiry date is not passed,
USE the vaccine

Unusable stage

The square matches or is darker than the circle.
DO NOT USE the vaccine
Inform your supervisor

A1.5 Why are VVMs important?

The VVM shows whether the vaccine vial has been exposed to excessive heat over time and it indicates whether the vaccine is likely to have been damaged by this exposure. Once the indicator reaches the **end point**, the vaccine should no longer be used.

A1.6 What types of VVM are available and how are they used?

Some vaccines are more sensitive to heat than others. For this reason, there are currently four different types of VVM designed to match vaccines with differing heat stability. For example, VVM 2 is used with OPV because this is the most heat-sensitive vaccine; this VVM reaches its discard point after only2 days at 37°C. In contrast, hepatitis B vaccine is very heat-stable and the VVM30 is used; it takes 30 days to reach its discard point at 37°C. The table below describes the four VVM reaction rates by category of heat stability.

VVM reaction rates by category of heat stability

Category	Time to end point at +37°C	Time to end point at +25°C	Time to end point at +5°C
VVM 30 High stability	30 days	193 days	> 4 years
VVM 14 Medium stability	14 days	90 days	> 3 years
VVM 7 Moderate stability	7 days	45 days	> 2 years
VVM 2 Least stable	2 days	Not applicable	225 days

Note that vaccines made by different manufacturers can have different heat stability characteristics and will be assigned to different VVM categories by WHO. For example, one manufacturer's BCG might use a VVM30 while another type of BCG may need a VVM14.

A1.7 Where is the VVM located?

VVMs are fixed to the vial or ampoule label of liquid vaccines which can be used in subsequent sessions under the Multi-Dose Vial Policy (MDVP). Where the vaccine cannot be used in subsequent sessions – for example, lyophilized vaccines such as MMR – the VVM is fixed to the vial cap or the neck of the ampoule. The VVM may also be fixed to the cap of mono-dose vials.