RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON COLD CHAIN MANAGEMENT

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GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	29/04/2021
ADOPTION BY RWANDA FDA	
STAKEHOLDERS CONSULTATION	
ADOPTION OF STAKEHOLDERS' COMMENTS	
DATE FOR COMING INTO EFFECT	

FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the missions of the Authority is to build cooperation and partnership for harmonization of practices with regional and international bodies with similar missions as stipulated in article 8, paragraph 15 of the above stated law.

Considering the provisions of the technical regulations Nº CBD/TRG/010 governing the registration of human medicinal products, regulations Nº CBD/TRG/011 governing control of medicated cosmetics; Regulations Nº CBD/TRG/012, governing registration of medical devices, Regulations Nº CBD/TRG/013, governing the registration of pesticides, laboratory and cleaning chemicals; regulations Nº CBD/TRG/015 governing the conduct of Clinical Trial, regulations Nº CBD/TRG/016, governing pharmacovigilance of pharmaceutical products and medical devices, and other relevant regulations, the Authority may rely on regulatory decisions from other regional and international regulatory authorities when deemed

necessary.

The Authority has developed guidelines on reliance for regulatory decision to promote a more efficient approach for regulatory oversight, access to quality-assured, effective and safe medical products. The reliance is an alternative /non-routine authorization pathway to the standard approval pathways - especially for applications where the safety and efficacy of the product have already been confirmed or when the Clinical Trial has been approved and/or initiated in a well –resourced regulatory authority (ies).

The reliance implies that the work done through Clinical Trial Assessment reports, Marketing Authorization (MA) assessment reports, GMP inspection reports, and Quality Control (QC) related decisions is shared by the well-resourced regulatory authority while the Authority uses this work according to its own scientific knowledge and regulatory procedures and retains its own regulatory responsibilities.

The reliance can be unilateral, bilateral (mutual) or multilateral for regulatory decision but the authority

maintains its own regulatory responsibilities for decision-making.

The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Dr. Charles KARANGWA
Acting Director General

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1. INTRODUCTION

Our capacity to respond to the needs of the populations we assist relies a great deal on the medications we administer and the tests we use for diagnosis. Some of these items depend on the cold chain, which is to say they must be kept at a temperature between 2°C and 8°C from the manufacturer to the patient. When there is a rupture in the cold chain not only does this simply waste money but, more importantly, it can jeopardise the quality of the diagnosis or treatment.

Good management of the cold chain presents us with two major challenges, which it is vital to address.

Firstly, the cold chain is a transversal family. Many aspects of its management rely on support from the logistics, but an equal number require support and monitoring from the members of the medical team. It is therefore important for each project

and mission to clearly define the various tasks and responsibilities.

Secondly, the cold chain is a “silent” family. Breakdown or incorrect use ofequipment will rarely lead to loud explosions or other dramatic events, the cold chain items will simply be damaged or rendered useless. It is therefore essential to monitor the cold chain regularly and rigorously.

1.1 OBJECTIVES

The objective of this document is to provide support for good management of cold chain in the missions. This document covers all the aspects which must be put in place to ensurehigh quality cold chain at all levels of the mission:

1. Divide responsibilities among medical and logistics departments.
2. Define a general manager of the cold chain.
3. Define tasks and assign them to appropriate personnel.
4. Supervise the proper adherence to cold chain procedures.
5. Dedicate a room to the cold chain (storage and preparation).
6. Use standard equipment to make managing it easier.

7. Develop a contingency plan, task lists and maintenance schedules.
8. Actively monitor the cold chain

1. ROLES AND RESPONSIBILITIES

Management of the cold chain is a collaboration between the logisticand medical teams. Clearly defining the different responsibilities is one of the most effective ways of improving the cold chain. When these responsibilities are clearly defined, tasks explained to those concerned, and closely supervised, the risk of breakdown is reduced and the chance that potentially damaged cold chain items are identified before they are used is very much increased.

1.1 DIVISION OF RESPONSIBILITIES

There are several steps which require responsibilities to be defined to maintain a high quality cold chain. These include transport, storage, monitoring, maintenance of equipment and correct use of the equipment. Each project should define these responsibilities in accordance with the activities and available resources. A central supply location will not define the responsibilities in the same way as a project health centre for

example. Here are a few suggestions for defining the responsibilities:

Transport & reception Equipment Storage Cold chain item storage

Daily temperature monitoring

Installation & maintenance

Log/Log Supply/Medical Storekeeper Log/Assistant Log/Storekeeper

Medical Storekeeper/Nurse/Cold Chain Log (vaccination campaign)

Principal user: Lab Tech/Nurse/ MedicalStorekeeper

Assistant Log/Maintenance Log

When the division of responsibilities has been defined create a task list which can be posted in the cold chain room, or anywhere else the equipment is used. There is an example task list in the annexes. The tasks should obviously relate to the equipment used and more information on this can be found in chapter 5.5 Maintenance (Reference).

2.1 ESSENTIAL TASKS

Temperature monitoring is the most essential task in the cold chain. The monitoring tools (details in chapter 6. Monitoring Tools) are the only indication we have of the quality of the cold chain. Temperature monitoring tasks should be the first tasks to assign. The national staff in charge of the medical stock is often the best choice.

The temperatures must be checked twice each day, 7 days a week, all yearround. In practice this can sometimes be difficult at weekends if the main responsible is not working. In many cases a rota of expat staff to do the checks on these days, or another member of national staff who is working, can resolve the problem. It is also necessary to assign a second responsible who will take over the monitoring during absences of the main responsible due to sickness, holidays or trainings.

Maintenance of the equipment will ensure it continues to work reliably. It is the logistic department, and specifically the maintenance log who oversees this. A checklist on the wall will help supervise that this is done regularly.

2.2. SUPERVISION

The cold chain is a family that requires regular, consistent supervision. Experience has shown that without supervision other operational pressures cause the monitoring frequency to decline over time and shortcuts to be taken in the procedures for using the equipment. In some cases, this has lead to almost daily cold chain rupture (which goes unnoticed due to lack of monitoring!).

2. HUMAN RESOURCES

Even the most perfect system is nothing without the active participation of the people who are involved. After assigning responsibilities it is important that the staff are given the means to achieve their goals. Train your coldchain managers to befter understand the wider issues, and their own tasks.

3.1. KEY FUNCTIONS

These functions are not positions as such but rather they define tasks which may be assigned to pre-existing ones. It is up to each mission to assign these tasks to positions which are best suited, according to the HR set-up of the mission.

The cold chain responsible is a key person. It is up to them to ensure the cold chain procedures are correctly followed, and that

the monitoring is done regularly. They must also organise staff cold chain training. Depending on the project the responsible will be the expat log, the supply chain manager or the mission pharmacist. The most important qualities are structured working method and discipline.

The preparer is the person who is responsible for transport betweenMSF locations; e.g. capital to project, or base to health centre. They will determine the correct choice of packaging (cool box or isothermal box) and the number of ice packs needed. No special skills are required but training is essential, and the person must work conscientiously.

The user is the last link in the chain from the manufacturer to the patient. It is they who must ensure the safe storage of the products in the final step. Often only passive cold chain (cool box or vaccine carrier) is used but this requires special aftention (see chapter 5.4). After the long journey they have taken to get this far it would be shaming to destroy cold chain items in this final step, but unfortunately this can easily happen unless procedures are followed to the lefter.

In the annexes you will find an exemple of a list of tasks for the cold chain, a responsibilities overview chart, and an exemple of a contingency plan. The respective tasks should be added

to the job profiles of the national staff involved of the monitoring.

3.2 TRAINING OPTIONS

Cold chain is integrated in various existing training courses, both logistic and medical. For a more in-depth training session which is tailored to the situation in your mission the flying cold chain technician or technical referent can also provide training, or send you training materials so that you can organise your own training sessions. During a visit session can be organised for different groups, according to their needs. The main training sessions are as follows:

General:

Overall training for all staff involved with cold chain.

Technical:

More in depth technical training for the logisticians.

Vaccination:

General training on vaccination campaigns.

Passive:

Training specifically for passive cold chain; use of cool boxes, vaccine carriers and icepacks for medical staff involved in health centres oroutreach activities.

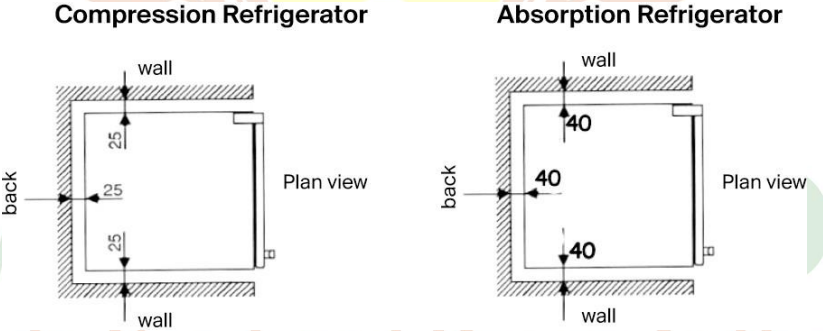
3. INFRASTRUCTURE

To facilitate the management of cold chain it is preferable to group theequipment together at the same place, in a dedicated cold chain room. This section of the guideline presents guidance on setting this up.

4.1 ARRANGING A COLD CHAIN ROOM

Dimensions

Refrigeration equipment needs space to avoid overheating and build-up of condensation. Leave at least 25 cm clearance around electrical equipment and 40 cm around equipment running on kerosene or gas. To facilitate cleaning and avoid accidental disconnection, leave the width of a broom.



To work well requires space and organisation. Provide enough space to easily transfer items between isothermal boxes, cool boxes and vaccine carrier to fridges and freezers. Correct conditioning of icepacks (chapter 5.4) takes space. A fixed table is best but a folding table which can be stored against a wall will allow you to save space when it is not needed.

Clean and well organized

MSF standard refrigerators and freezers (Vestfrost series MK and MF; Sibir), although tropicalised, are not indestructible! A clean room prevents dust, dirt and waste from damaging the equipment. Furthermore, absorption (Sibir) refrigerators run on kerosene or gas and produce a flame, badly organised or dirty cold chain room will increase the risk of accidents or fire.

It is easier to work, and work more efficiently, in a well organised room.

Remove all equipment which is not related to the cold chain. This also avoids unauthorized personnel needing access, which will make it easier for the cold chain responsible to do their job well.

Dry and well ventilated

The ideal temperature for fridges and freezers is roughly between 20°C and 35°C. Above 35°C the equipment will have to work harder to maintain correct temperatures. The MSF standard equipment is befter suited to hot environments as it is tested to 43°C. Ensure that hot air can escape by placing ventilation openings high on the walls. The equipment itself will produce heat so avoid installing additional heat sources, except in countries where the ambient temperature drops below freezing. In these cases, heating is needed to keep the ambient temperature from dropping below around 10°C.

Absorption type refrigerators like the Sibir produce heat by burning a fuel. Unless the fumes can escape, and fresh air is let into the room the burning process could be affected and poisonous fumes could build up.

The roof, floor and walls must be waterproof. The equipment (especially rubber seals) is sensitive to moisture build-up which can cause mould to grow. Additionally, electricity and water do not mix well… avoid short circuits!

Restricted access

The cold chain contains items which are not only sensitive but can be valuable too. In many countries where MSF intervenes there are well established black markets for drugs

and medications. Fridges are often scarce and cold water very much in demand in hot countries. Securing this room ensures that only those responsible or authorised have access. This provides befter stock security and helps avoid accidental disconnection or bad practices that could lead to rupture. In addition, the less often a fridge is opened the more stable the inside temperature will be.

The door of the room must therefore be secured using a lock or a padlock, and the key must be entrusted only to authorized individuals. If it is notpossible to lock the room then lock the fridges and the freezers.

4.2. ENERGY

The generator Check that the generator can supply all the equipment. Use the generator calculation tool provided by the technical support service.

An electrical back-up

Whether the installation is supplied by city power or by a generator make sure there is a backup system. This can either be a small generator dedicated to cold chain or a larger generator as general backup for the whole electrical system. Apply the same rules of dimensioning as above.

For ice-lined fridges, such as those from Vestfrost, there is no need to install inverter systems to ensure permanent electrical supply. These fridges have a hold-over time which is sufficient for maintaining cold chain temperatures with approximately 8 hours of electricity per day. Every additional item of equipment in the electrical supply can potentially increase the chance ofa failure.

Electrical safety

The circuits which supply the cold chain must conform to the electricalstandards of MSF-OCG.

Earthed

Differential protection

Correct sizing of cables and circuit breakers

Install a circuit breaker which is dedicated to the cold chain circuit. This avoids needing to disconnect if there is work on other circuits.

Circuits, circuit breakers and power outlets for the cold chain room must be clearly labelled and secured against accidental disconnection.

Keep in mind that electrical freezers and refrigerators (for example theVestfrost series MF and MK) require five times

more power to start thanwhen running, potentially overloading the electrical system. If necessary, install delay timers (PELETEMP01)-, these devices allow the equipment to start one after the other rather than simultaneously.

If the voltage of the electrical system is unstable then connect the equipment through voltage limiters/stabilisers (PELEVOLS250).

Install a light bulb in the cold chain circuit and mount it outside the cold chain room in a clearly visible location. This allows quick visual verification of the electrical supply to the cold chain. It's best to connect the light to the same socket to which the fridges are connected, so that gives a true indication of whether the fridges are receiving power. Like this it will also indicate any issues with circuits breakers, differential protection or voltage stabilisers etc. For more information on correct the dimensioning of electrical installations, generators, back-up systems and electrical safety, refer to the Energy

Guideline or ask the technical support department of MSF-OCG.

4.3 SIGNAGE

Post the following items on the walls of the cold chain room to ensure thatthe necessary information is available:

Packing instructions

Contingency plan

Task list

Reminder of the rules for the preparation of isothermal boxes, cool boxes and vaccinecarriers. This avoids errors.

Reminder of the procedure to be followed in theevent of extended power outage or equipment failure (info in chapter 7. and example in theannexes).

Check list daily, weekly and monthly tasks by those responsible for the cold chain (info inchapter 2. and example in the annexes).

It is important to display only the essential information and to update it regularly to reflect any changes (especially the contingency plan).

Display the following on each piece of equipment (fridge, freezer etc.) tofacilitate the management of cold chain:

4. EQUIPMENT

Cold chain equipment is divided into 3 main groups; active cold chain (which produces cold), passive cold chain (that maintains the cold for a limited time without energy) and temperature monitoring tools that allow us monitor the quality of the cold chain.

5.1. SELECTION CRITERIA

The choice of equipment must meet the following criteria:

The medical activities

The cold chain must meet the needs of a medical activity, as defined by the medical programme. The logistics and medical teams must work togetherto find the most suitable solution. See Division of Responsibilities in Annex

II. Management Tools for details.

Storage volume

The storage volume of refrigerators is specified in litres. There are twovalues, a gross value and net value. The net value is the maximum quantity of medicines/vaccines that a refrigerator may contain using the storage baskets. The gross value is the maximum quantity of medicines/vaccines that a refrigerator may contain if the full space is used, without baskets. The gross volume may only be used temporarily and only in

case of emergency (breakdown of another fridge) or during a vaccination campaign if there is insufficient storage space.

Quantity of icepacks needed

Passive cold chain requires icepacks. The freezing capacity of the freezers must therefore be matched with the rate of consumption of icepacks. This is normally done using the (compression type) freezers because absorption fridges have very limited freezing capacity. In remote locations with only

a small stock of cold chain products a fridge with integrated freezer compartment may be the best solution. Be aware that in some cases (notably absorption fridges like the Sibir) the temperature in the fridge compartment can rise when icepacks are being frozen.

Available energy sources

If the project has 8 hours or more electrical energy per day then always opt for the ice-lined refrigerators (for example the Vestfrost). Icelined fridges can maintain temperatures between +2°C and +8°C for 10 hours or more (depending on the exact model) without power.

Where there is no city power and a generator is not an option you can consider solar, gas or kerosene powered equipment. Consider also thatthere are often restrictions on air transport of boftled gases, and the quality of fuels (such as gas

or kerosene) which can be found locally may not be high enough to guarantee reliable functioning of the equipment.

When deciding on equipment for a project consider also how suitable the equipment would be for donation in case of closure of the project. Anyequipment donated must usable and maintainable by the organisation to which it is donated. Fuel and spare parts must ideally be readily available and inexpensive.

5.2 SUPPLIERS

Our supplier for cold chain equipment is MSF-Logistique in Bordeaux. It is forbidden to use equipment which is not MSF standard, or at least medical grade. The reason is simple: MSF standard equipment is medical equipment whose sole purpose is cold chain. Domestic refrigerators are designed to store food and drinks; these devices do not guarantee atemperature between 2°C and 8°C. This is true both for active cold chain and for passive cold chain equipment.

The use of unsuitable equipment will, soon or later, lead to a cold chain break, so it must be replaced with standard equipment! Any use of non-(MSF) standard equipment must first be technically validated at HQ level.

Domestic fridges must only be used in case of emergency, and then only with precautions taken to decrease the risk. Details of the precautions to be taken are given in chapter 7.3 Contact your CoTL/Cell and technical referent for advice before using.

You will find the list of MSF standard equipment in the catalogue ITC (familycode PCOL).

5.3. IDENTIFICATION

To facilitate easy management of the equipment it is useful to tape identification sheets on the equipment of active cold chain (Annex III. ID Sheet). These fact sheets summarise the main characteristics of theequipment:

ID number:

Easy to check against the inventory

Make, model and serial number:

Again, for inventory verification

Storage volume (net and gross):

Easy to confirm required storage volumes for orders etc

Hold-over time of the equipment:

Guaranteed time the temperature will remain below 8°C following a poweroutage

Freezing capacity per 24h:
Needed to calculate the production capacity for icepacks

Check-list of required monitoring tools:
To make sure none are forgoften!

In the case of vaccination campaign involving numerous teams, it may be useful to assign a number to each team and stick this number on the coolboxes and vaccine carriers.

5.4. USE

There are specific rules for using different cold-chain equipment. These rules are designed to ensure high quality cold chain. Refrigerators and freezers are collectively referred to as "Active Cold Chain" because they require a source of energy from which they produce cold. Isothermal boxes, cool boxes and vaccine carriers are collectively referred to as "Passive coldchain" because they do not produce cold but will preserve it for a limited time. They are detailed below:

Refrigerator

The use of baskets is mandatory; this avoids the cold chain items cominginto direct contact with the walls of the fridge, eliminating the risk of freezing by contact. Leave some space between the boxes as this ensures good circulation of the air. Ultimately this helps ensure a homogenous temperature inside the fridge.

Boxes should be stored according to the standard FEFO (First Expired, First Out). The products with the soonest expiry date should be the most accessible, ensuring they are used first. This will help to limit the loss due to expiration.

The cold chain items which are most sensitive to freezing should be placedas far as possible from the coldest part of the fridge. The coldest part is near the evaporator, which is what introduces the cold inside the fridge. It is usually located at the top rear of the upright models (Sibir) and in the walls at the boftom of the chest type models, near the compressor (Vestfrostetc.) but check the manuals to be sure.

When first using a refrigerator, you must let it stand 24 hours after transport before connecting it. Then switch it on with the thermostat on maximum for a further 24 hours, this allows the ice-lining to cool. After that turn the thermostat down and

monitor the temperature as it stabilises. When thetemperature is stable at around 5 to 6 °C put tape over the thermostat dialto prevent is being changed accidentally. The fridge may now be used.

Freezer

In MSF freezers are generally only used for producing and storing the icepacks needed for passive cold chain. Ensure you always have enough frozen icepacks and anticipate any changes in the number of icepacks required because producing ice is time consuming.

When there is a need for icepacks you must also take into account the freezing capacity of the freezer. For each type of freezer the number of kg of ice that can be produced per 24 hours is listed in the technical data. Loading more icepacks than can be frozen in 24 hours will result in chilled or only partially frozen icepacks. The best practice is to load half the volume in the morning and the second half in the evening. Freezers should be setto -20°C.

Isothermal boxes, cool boxes and vaccine carriers

Isothermal boxes, cool boxes and vaccine carriers are collectively referred to as “Passive cold chain” because

they do not produce cold but areintended to preserve it for a limited time. It is essential to not only pack correctly, but to have the correct volume of ice (icepacks) inside.

There are different makes and sizes of cold chain certified equipment that you may find in the field and the autonomy (hold-over time) varies greatly. An RCW25 for example will have autonomy of around 5 days if unopened whereas a vaccine carrier will last only about 1.5 days, under the condition that the equipment is not exposed to direct sunlight. Check that the hold- over time is sufficient for the planned usage before using the equipmentfor any purpose. Packing instructions can be found in the annexes.

In passive cold chain equipment, the icepacks must be physically separated from the drugs to prevent direct contact. You will find blueprints in annexesfor making containers for this from unused isothermal boxes.

The foam piece that is supplied with a vaccine-carrier is very important. It has slots into which you can insert open vaccine vials. This allows them to be kept cool while at the same time avoiding heat exposure of the entire vaccine carrier content

each time the lid is opened. For daily use place theopen vials in the foam and close the lid again after filling a syringe.

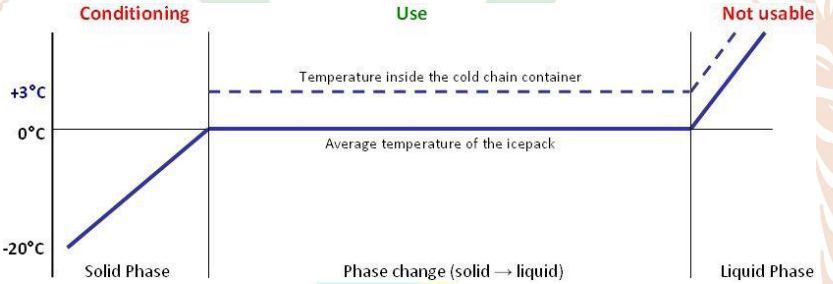
Icepacks

The icepacks are the source of cold in isothermal boxes, cool boxes andvaccine carriers. When you receive new icepacks, they will be empty tosave transport weight. Only ever fill them with water. Other liquids have different freezing points and using them will risk cold chain ruptures! Never fill icepacks to the top because there must be space to allow for the water expanding as it turns to ice. There is a fill level mark on each icepack.

Icepacks must be stored cap upwards to prevent leakage. Always leave aspace between the icepacks in the feezer, these expand as they freeze andbecome impossible to remove if they are tightly packed. In the worst case this can damage freezer compartment walls. Place them against the walls (on either side with a gap in the middle) as this will optimise the freezing.

If icepacks are taken straight from the freezer and placed directly in theequipment being used it will freeze the content and keep it frozen for a number of hours. It is therefore essential to prepare icepacks (called conditioning) before

placing them in the passive cold chain equipment. Conditioning is done to bring the icepacks to a state where they will have an average temperature of around 0 °C instead of the temperature theyhave when taken from the freezer (usually around -20 °C).



Conditioning icepacks is done simply by removing them from the freezer and leaving them outside the freezer for a certain length of time. Conditioning should be done as follows:

Remove the ice packs from the freezer and spread them out on a table. Using a table makes the task easier and will help keep them clean, to avoid making the inside of the cold chain container dirty.

The table should be in the shade so as to avoid direct sunlight falling on the icepacks.

The icepacks should not be stacked as this will prevent good conditioning.

Conditioning must always be done in air (in a well-ventilated location), never in water (for example in a bucket). Using

water can give theappearance that the icepacks are conditioned but in reality, they are not. Only the outside layer will be partially melted, when the icepacks are removed from the water the melted water can re-freeze. In addition, the water being used will gradually cool and become less inclined to absorb cold from the icepacks. When conditioned in air the icepacks will not cool the air significantly, especially if there is good ventilation.

The length of time needed depends on the ambient temperature and the temperature of the icepacks when taken from the freezer. There are a few different recommendations for how to decide if the icepacks are conditioned and ready to be placed inside the cold chain container:

Recommendation	**Advantages**	**Disadvantages**
Wait until there is a small amount of water visible in the boftom of the icepack.	Easy to apply in any context without prior testing.	Very subjective; what is a small amount? Difficult to achieve consistent results so not recommended.
Wait until the droplets of condensation on the outside of the icepack are no longer frozen.	Easy to apply in any context without prior testing.	The amount of condensation depends on the relative humidity (water in the air). Difficult to achieve consistent results so not recommended.

Use predefined conditioning times, based on ambient temperature.	Easy to apply in any context and provides consistent results.	Temperature table will often cover a range of ambient temperatures. This will not cause problems if the longest conditioning time is respected.

General rules of thumb for icepacks:

The length of time that the icepacks are conditioned defines the lowest temperature reached inside the isothermal box / cool box /vaccine carrier. The shorter the conditioning time, the lower the inside temperature.

The number of icepacks used will influence the autonomy of the isothermal box / cool box / vaccine carrier (up to the time limit specified in the packing instructions). The more icepacks you use the longer the equipment will maintain an inside temperature between +2°C and +8°C.

4.1 MAINTENANCE

There are different maintenance tasks which must be done regularly to ensure the equipment will function reliably. Full details of these tasks - and more information on how to do them - can be found in the technical documentation and guidelines, and in the example task list in the annex. Below is a brief overview to give an idea of the most important tasks.

Electric/solar refrigerators:

Clean inside and remove any condensation.

Clean the solar panels (to ensure they provide enough power for the fridge).

Clean the outside of the equipment (don't forget to remove dust from the condenser at the back) and remove dust from the

compressor compartment (behind the protective grill). This ensures heat can escape from any surfaces which get warm. The lifespan of the equipment will be reduced of cooling is obstructed by dust and dirt.

Verify that power connections and switches/thermostat is securedagainst tampering or disconnection.

Check the door seals by trying to slide a piece of paper between the seal and the fridge body (it must not slide easily). If necessary clean the seal and lightly dust with talcum powder. A good door seal helps prevent cold loss and avoids moisture build-up inside the fridge.

Gas/Kerosene refrigerators:

Clean inside and remove any condensation.

Check that there is enough gas/kerosene in the boftle/reservoir.

Clean the outside of the equipment.

Clean and remove dust from the back of the equipment, the chimneyand the burner. That will ensure a good airflow, which is needed for the burner to function well.

For kerosene refrigerators check the general condition and the adjustment of the burner and trim/adjust the wick if needed.

Check the door seals by trying to slide a piece of paper between the seal and the fridge body (it must not slide easily). If necessary, clean the seal and lightly dust with talcum powder. A good door seal helps prevent cold loss and avoids moisture build-up inside the fridge.

Freezers:

Defrost and clean inside if the layer of ice is more than 5mm thick. This ensures optimal freezing capacity and avoids damage to the freezer. Keep the icepacks in a cool box while defrosting to avoid having to completely refreeze them when they are put back.

Clean the outside of the equipment, dust off the condenser on the back, and remove dust from the compressor (behind the grill). This ensures that surfaces that may become hot can release the heat. If this is not done the equipment will not operate long or reliably.

Check the door seals. If necessary clean the seal and lightly dust with talcum powder. A good door seal helps prevent cold loss and avoids moisture build-up inside the fridge.

Cool boxes and vaccine carriers:

Check the door seals. If necessary clean the seal and lightly dust with talcum powder.

Check the general condition of the equipment to be sure there is no damage to the case or hinges. That can seriously reduce the hold-over time.

Clean the equipment inside and out.

When not used for long period:

Cool box - Make sure it is clean and dry. Remove and talc the seal then places it inside the cool box. Store cool boxes with a piece of wood tohold the lid open and allow air circulation which will prevent moisturebuild-up. Multiple cool boxes can be stacked.

Vaccine-carrier - Make sure it is clean and dry, talc the seal but leaveit in place. Place the lid and the foam in the vaccine-carrier and storeit. Multiple vaccine carriers can be stacked.

Isothermal box - Make sure it is clean and dry and undamaged, ensure all the foam inserts for icepack separation use are in goodcondition and there is no damage to the box itself (otherwise it shouldnot be re-used) and store it.

Posting a follow-up sheet for maintenance work will allow the maintenance technician to sign-off each time the work has been done and simplifiessupervision of these activities.

5.5 REPAIR

In case of breakdown of a refrigerator there are technical guidelines which will assist in finding the cause of the breakdown. Only original spare parts should be used for repair, for MSF standard fridges these are available from the supply centre. You may find repair services locally, but they are most often repairs are badly done. Only do this in an emergency and

ensure theyuse original parts and materials for the repair. Using the wrong parts or a badly done repair can turn a fridge into a freezer!

5.6 MANAGING EQUIPMENT OWNED BY OTHERS

In some projects you may find existing cold chain fridges belonging to partner organisations such as an MoH. The equipment must conform to the same standards that MSF applies to our own cold chain, i.e. they must be medical standard. It is best to test the equipment using a LogTag to get an idea of the temperature stability and homogeneity before using themfor storage of MSF cold chain products.

5.7 DONATIONS

On occasion UNICEF or other organisations may offer cold chain equipment as a donation. It must only be accepted if it meets the standards set by MSF for cold chain use. This includes all equipment which is listed in the MSF catalogue. Other equipment may also be acceptable but before accepting you should get advice from the technical referent for cold chain beforeaccepting it.

If you are closing a project and there is equipment which you wish to donatethen verify that the organisation to which you want to make the donation has the means to use it well. That means sufficient funds for fuel and spares, and the knowledge to use it

correctly. If not, there may be other organisations (in the capital or in other projects) who could make befter use of it.

5. MONITORING TOOLS

Close monitoring of the cold chain is essential. Without active monitoringit is impossible to know how well the equipment is functioning or beingused, and therefore to know if the cold chain items are still useable. The equipment must be monitored continuously; twice per day, 7 days a week, 365 days a year. For cold chain transport the monitoring tools must be checked immediately upon receipt of the shipment.

6.1. THERMOMETERS

Thermometers give an instantaneous indication of temperature; they do not provide historical information (except max/min thermometers). Used in conjunction with a temperature follow-up sheet they are the simplest way to follow temperature over time. The main types are alcohol (fridges and freezers), and liquid crystal (cool boxes and vaccine carriers) and electronic.

6.2. TEMPERATURE FOLLOW-UP SHEET

This is the form used for recording the temperature of a refrigerator or a freezer. There are several formats in circulation that can be chosen depending on your preference. The most important thing is to use it atleast for each fridge, and to record readings 2 times per day, ideally +/-12 hours apart.

6.3. FREEZETAG

This tool shows when the temperature has beenbelow 0°C for 60 consecutive minutes. It is irreversible so once in alarm state it cannot bereused. The "√" symbol indicates that all is well, an "X" indicates an alarm.

The small dot in the lower right of the display blinks to confirm that thebaftery is okay and the device is functioning. If this changes or the device goes beyond the expiry date marked on the casing, it must be changed asit is no longer reliable.

6.4. 3M CARD

It is an irreversible indicator of exposure to heat. The windows turn blue one by one as the heat exposure increases (A, B, C, D). Each drug has a different thermo-sensitivity so you must refer to the tables in the medical ITC catalogue for information on which indication signifies a damaged product for each individual drug.

6.5. STOPWATCH!

The Stopwatch! is basically a FreezeTag pasted on a 3M Card. It is the best solution for use in refrigerators because it can easily be aftached to the basket to keep it from slipping down bet

6.6. LOGTAG

The LogTag is a fully programmable temperature recorder. It allows you to review the evolution oftemperature over the past period and displays thisas a graph in the software provided. The basic model has only an alarm lamp, so the rest of the data must be accessed using a computer. For more details, refer to the manual.

There a various models:

Basic model with two LEDs (green for “OK” and red for “Alarm”).

Model with humidity recording function in addition to temperature formonitoring conditions in medical stocks.

Model with a display which as well as recording provides an instantaneous temperature indication. This can be use as a combined

6.7. VACCINE VIAL MONITOR (VVM)

The VVM is an irreversible indicator of exposure to heat, similar to the 3M card. It consists of a white square in a grey circle or purple. The longer the vial isexposed to heat the more it darkens. As long as the square is lighter than the circle the contents of the vial are okay as long as they have not been frozen. If the square is darker than the circle the vial contents must not be used.

6.8. USE OF TOOLS IN THE DIFFERENT ITEMS OF EQUIPMENT

The following table shows which tool to use depending on the situation:

Equipment	Thermometer	FreezeTag	3M Card	Log Tag	Temperature follow-up sheet
		Or StopWatch!			
Refrigerator	Compulsory	Compulsory	Compulsory	Compulsory	Compulsory
Freezer	Optional	Unnecessary	Unnecessary	Unnecessary	Optional
Isothermal box (transport)	Unnecessary	Compulsory	Compulsory	Compulsory	Unnecessary
Cool box (transport)	Unnecessary	Compulsory	Compulsory	Compulsory	Unnecessary
Vaccine carrier (transport)	Optional	Compulsory	Optional	Compulsory	Unnecessary
Cool box (Vaccination)	Compulsory	Compulsory	Unnecessary	Optional	Unnecessary
Vaccine carrier (Vaccination)	Compulsory	Compulsory	Unnecessary	Optional	Unnecessary

7. ORGANISING TO AVOID PROBLEMS

When planning your cold chain emergency strategy there are three main points to consider. Most importantly there is the contingency plan, which lists the set of actions to be undertaken to prevent a rupture in the event of power or equipment failure. Secondly the task list that describes the daily, weekly and monthly activities which will ensure a quality cold chain, and the maintenance record sheet. These documents should be displayed in the cold chain room to facilitate supervision. Finally there are the spare parts or equipment which can be kept in stock for repairs or equipment replacement.

7.1. CONTINGENCY PLAN

The contingency plan is the list of actions to be taken in case of a power failure, or of equipment malfunction. It must answer the following questions:

Thinking about, and finding answers to, these questions before the problem arises means you will not lose time when the situation actually happens. In addition, this allows you to ensure you have the material necessary for the implementation of the contingency plan. It is clear that this equipment (e.g. cool boxes, icepacks etc.) must be always available.

You will find a sample contingency plan in the **Annex II**. Management Tools.

7.2. TASK LIST

The task list is the checklist of tasks that must be carried out (every day, every week and every month) by the various people according to their responsibilities and supervised by the cold chain responsible. Although many tasks are universal the list must be adapted according to the equipment used in the project. The basic content must include:
You will find a sample task list in the Annex II Management Tools.

7.3. SPARE PARTS AND BACK-UP EQUIPMENT

The MSF standard refrigerators are usually reliable but as this equipment can be quickly damaged by low quality electrical supply it is wise to have some spare parts in stock. These can also be ordered from the supply centre. Having spares in stock will enable you to repair the equipment yourself, or to ask a local repair service to do the repair with the spare partsyou provide (see chapter 5.6 Repair).

Recommended spares (for each type of equipment) include:
Starter relay (refrigerator/freezer, all electric models)
Fuses (refrigerator/freezer, all electric models)
Thermostat (refrigerator/freezer, all models)

Burner and glass (kerosene fridge)

Solar charge regulator (refrigerator/freezer, solar models)

Baftery (refrigerator/freezer, solar models)

When making or updating the contingency plan you will find out where you can find (temporary) replacement equipment. This is usually other NGOs ororganisations., or preferably your own mission back-up equipment.

If there are no suitable options, you should consider the following alternatives. They are listed in order of safety for the cold chain products; the first option being the safest (provided the correct procedures for use are followed):

Use the RCW 25 cool boxes. When kept closed they have an autonomy of 5 days. Ensure that there are enough cool boxes available to cover the storage volume needed and enough frozen ice packs available.

Use the gross storage capacity of the functioning refrigerators. Ensures that vaccines that are sensitive to freezing are not placed in the coldest part of the refrigerator (the lower part, close to theevaporator).

Use a domestic fridge. This potentially poses risks which must be addressed:

Forced circulation of cold air - some model of fridge use fans to blowcold air into the fridge compartment. This risk freezing productswhich are placed in front of the fans because the air is often taken directly from the freezer compartment. Place shields in front of the openings to deflect the air sideways.

Unequal temperature distribution in the fridge compartment - ensure that there is space between the boxes placed inside to allow the air to circulate freely.

Automatic defrost feature - Fridges with this feature must be avoidedas it will cause a warming of the fridge periodically.

No hold-over time, need constant power source - domestic refrigerators have much less insulation than medical standard ones and they have no ice-lining to increase the autonomy when thepower is off. Never use the trays in the doors, nor in the vegetable compartment in the boftom, for cold chain items. Fill them with non- frozen ice packs to provide a "stock" of cold which will extend the autonomy.

8. IN CASE OF RUPTURE

Cold chain rupture is when the cold chain products are exposed to temperatures above 8 °C or below 2 °C.

Only regular checking of the temperature monitoring tools (see chapter 6. Monitoring Tools) can detect a cold chain rupture in time, before there is any danger of destroying or degrading drugs/vaccines/tests.

If one of the monitoring tools in the cold chain indicates a problem these are the steps which must be undertaken immediately.

Gather as much information as possible about the reasons for thebreakdown.

Download the LogTag data.

Place the suspect items in quarantined cold chain where they remainuntil the final decision on their condition is reached.

Inform the logistic and medical responsible (MTL, MedCo, LTL, LogCoetc.).

The medical responsible or the pharmacist should make a test on thesite (shake test, visual observation, test with a tester etc.).

Write a report including the results of the tests using the form "MSF OCG Cold Chain Break Down Report.doc".

Send all documents (report of rupture, the test results, specificationsof logtag etc.) to the email addresses that are noted in the document "MSF OCG Cold Chain Break Down Report.doc").

For breaks during international transport (under the responsibility of MSF-Logistique) fill in the document "Reclamation-Claim.doc" and send it to the person at MSF-Logistique who is responsible for the shipment in order to make a claim.

ANNEXI

Definition of Terms

Cold chain (CC)

A system to ensure the quality and safety of certain medical products that need to be kept at a strictly controlled temperature from supplier to the population. It comprises many different steps of transport and storage and consequently many people are involved. For MSF (and according to the pharmaceutical definition) the temperature range for cold chain is between +2°C and +8°C.

Cold chain products

Medical items (e.g. certain vaccines, tests, and drugs) which have to bestored and transported under cold chain conditions.

Rupture de la chaîne de froid

Cold chain rupture

A breakdown in cold chain, either during storage or transport, is defined as exposure to temperatures above +8°C, or below +2°C. A rupture does not always result in destruction of cold chain products, but the products must be quarantined and kept in cold chain until an advice has been given by the HQ responsible.

Active cold chain

Equipment which can produce cold (refrigerators, freezers)

Passive cold chain

Equipment which can keep cold for limited time (ice pack, cool box, vaccine carrier, isothermal box etc.)Outils de contrôle

Monitoring tools

Tools for T°C follow up (thermometer, follow-up sheet, 3M card, freeze tag,LogTag etc.)

Cold chain responsible

Person in charge of cold chain follow-up and reporting (reception, storage,transport, T°C monitoring).

Contingency plan

A document which describes the possible solution (what to do) in case of cold chain equipment failure.

Task list

A document specifying daily, weekly and monthly responsibilities (tasks to do) for cold chain responsible and for log maintenance responsible.

Country Specific Policy (CSP)

A document wriften specifically for a mission and which defines the overallpolicy as applied in the mission. A CSP may never contradict any aspect ofthe overall MSF-OCG Policy.

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anda Food and Drugs Authority

SELECTION & PURCHASE OF EQUIPMENT		BEFORE STARTING WITH COLD CHAIN	)URING USE	IN CASE OF PROBLEMS
Based on POA identify for which medical activities cold chain is needed: Which sites need Active cold chain (*fridges, freezers*) size of Passive cold chain equipment (*transport or temporary storage*)		Conduct general cold chain training for medical staff fully involved in cold chain. Conduct basic/reduced cold chain training for medical staff only partly involved in Cold chain.	Responsible for: storage (and verification for orders) transport preparation/ packing reception (Supply in some locations) temperature monitoring (*including LogTag data recording)* site of use)	Identify the problem & provide LOG with: - Description of problem Indication of urgency
Calculation of volume of cold chain products (*in dm3 or litres*)		Identify staff responsible for a central cold chain. If there are	Use the equipment and perform users care in	-

which need to be stored at each cold chain site *(use EasyMed)*		multiple sites with cold chain at the project, identify a responsible for each of the sites.	accordance with the agreed procedures. (*see: Task list*)	
Based on: information from Medical about the medical activities (*type of cold chain needed*) information from Medical about a volume/quantity of cold chain products need to be stored ice packs production needs for Passive cold chain equipment type of available	Follow the order through the supply system and give feedback on delivery to MED. Prepare the project structures for Active cold chain equipment (i.e. energy, room/building layout, back	Conduct training for medical staff in user's responsibilities with cold chain equipment. Conduct training for log staff in preventive and corrective maintenance of cold chain equipment. Conduct general training for Log staff involved in cold chain. Prepare "Contingency plan" (*back up plan for cold chain equipment*	Responsible for: execution of transport storage of not used cold chain equipment & tools Perform preventive and corrective maintenance in accordance with the agreed procedures. (*see: Task list)* Ensure that inventories are kept updated to reflect any	Assess problem and propose solution.

energy Logistic department will choose the most appropriate type and size of Active & Passive cold chain equipment.	up power, staff training, etc.) Take delivery of the equipment and manage its installation. Enter equipment in inventory.	*failure*) and make a briefing for staff involved (medical & log). Prepare "Task list" (*daily, weekly, monthly task to do*) and make a briefing for staff involved (medical & log).	changes in equipment (and status). BE AWARE: hat in case of accination ampaign it is usually ogistic which takes n charge complete old chain a part rom handling of cold hain products at accination site	

Medical responsibility Logistics responsibility

CONTINGENCY PLAN

MSF-OCG Guideline - Cold Chain Management

Contingency Plan (example)

Cold chain - Contingency plan – POWER FAILURE

If the generator fails contact the following persons immediately:

- First contact, Agok log base, mobile number :
- Then contact, Agok log supervisor, mobile number:
- Then contact, Agok Fieldco, mobile number:

!!! TASKS bellow are DONE by LOGs or LOG ASSITANT or Field!!!

- Juba LogCo, mobile number:
- If not the generator available, try to borrow one from other
- If not possible to have generator from another NGO in Agok ask Abyei for Yamar generator

Cold chain - Contingency plan – FRIDGE BREAK DOWN

If CC equipment fails, contact the following persons immediately:

- First contact, Agok log base, mobile number:
- Then contact, Agok log supervisor, mobile number:
- Then contact, Agok Fieldco, mobile number:
- Juba LogCo, mobile number:

!!! TASKS bellow are DONE by LOG or NURSE or LOG ASSITANT!!!

Temporary storage of cold chain items before finding a permanent solution

- If one fridge breaks down: the most sensitive items must be placed in the fridge that is still working. Other items have to be placed in cool boxes.
- If all fridges break down: all items have to be placed in cool boxes. Before putting ice packs in cool box, they must be conditioned (in pharmacy temperature of 25°C) for 60 minutes (only trained person should do the loading to avoid freezing of items/vaccines)
- Items must be separated from the ice packs by an isolating card board.
- T° monitoring devices have to be put into cool box: FreezTag, Thermometer, LogTag
- The temperature must be then monitored on an hourly basis.
- In case that the problem of the fridge is not solved before T° in cool boxes raised over 8°C and there is no more ice packs for rotation:

1)borrow a fridge from other NGO or use storage capacity at their site

2)use freezing capacity of other NGO for our ice packs rotation

3)ask Abyei for their kitchen fridge MK144 (clean it properly before use – disinfection)

MSF-OCG Guideline - Cold Chain Management

Daily, weekly and monthly check list (example)

Person responsible during the week: back-up person:

Person responsible during the weekend: back-up person:

Daily check

Morning - 0830am

Verify that there is electricity power supply available + that plugs are connected

Check temperature on all fridges (between 2° - 8°C)

Register temperatures into relevant follow up sheets

Check that there is OK light (green) on LogTags in the fridges (if red light - download and check data immediately – inform the supervisor)

Prepare ice pack 0.4L for various wards (6x0.4L ice pack per one vaccine carrier) – conditioning 30”-40”

Every second day - prepare ice pack 0.6L for Laboratory (12x 0.6L ice pack per one cool box) – conditioning 60”

Are there any strange noises?

Is there water on the floor?

Evening - 1900pm (*after generator power is back*)

Verify that there is electricity power supply available + that plugs are connected

Check temperature on all fridge (between 2° - 8°C)

Register temperatures into relevant follow up sheets

Check that there is OK light (green) on LogTags in the fridges (if red light - download and check data immediately – inform the supervisor)

Are there any strange noises?

Is there water on the floor?

From 1900 PM – 8.00 AM

- Guards hourly check the control light (if no light inform log base immediately)

Weekly check

In addition to the daily check:

- Ice layer above 5mm? *Defrosting and cleaning if necessary*
- The contingency plan with contact persons and phone numbers is attached AND IS UP TO DATE
- RCW boxes and carton for separation ice packs/vaccines are ready in a case of emergency (fridge failure or maintenance/defrosting)
- That there is enough frozen ice pack available in a case of emergency
- Ice packs, which are not used, are properly stored

Monthly check

In addition to daily and weekly check:

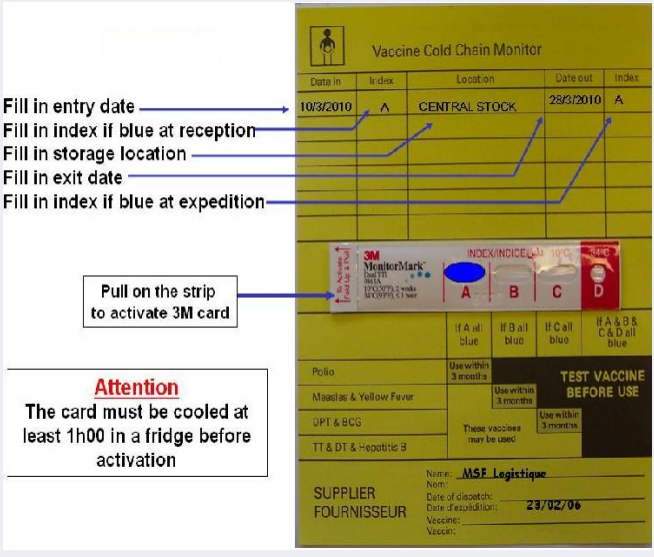
- Change temperature follow up sheets and store the old sheets in a filer (folder)
- Download data from LogTag from each fridge (keep records)
- Clean the cold-chain equipment (dust in the back from condenser, if needed wash lightly the fridge)

- Check the door seals (use paper) and clean the door seal
- Check that electric plugs and switches for the cold chain equipment are marked and secure against accidental disconnection.
- Electric cables are properly mounted and protected against water

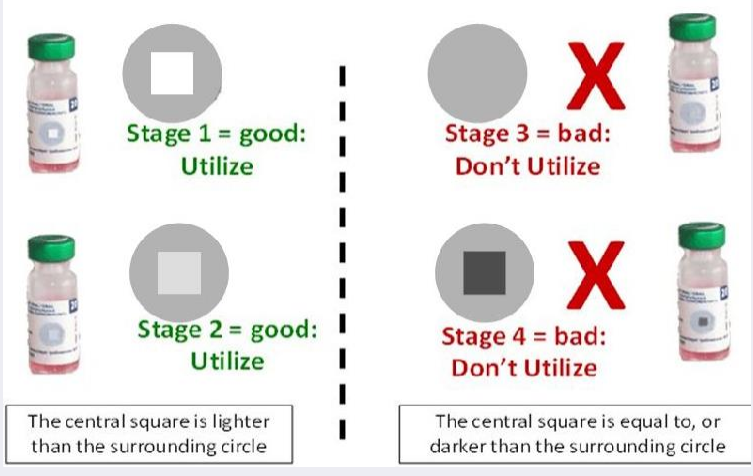
Backup system is in place: generator

Report any irregularity immediately to your supervisor according to the contingency plan.

3M Card



Vaccine Vial Monitor VVM



SHAKE

Has your vaccine been damaged by freezing?

Freezing damages the potency of DPT, DT, Hep B, and TT vaccines. It is important to identify when vaccines have been damaged by performing the steps below.

Regularly inspect your vaccine refrigerator for signs of freezing. If you suspect that vaccine has been frozen, use the shake test to determine whether the vaccine should be used (any vaccine that is frozen solid or is not homogeneous should be discarded immediately).

Inspect the Freeze Watch™ indicator and monitor the refrigerator temperature for signs that storage conditions have dropped below freezing.

FREEZE-TAG

Do you suspect the vaccine has been frozen?

YES

Thermometer

Has the temperature dropped below freezing?

YES

YES

Conduct the shake test.

1. Select one sample from each type and batch of "Suspect" vaccine. Freeze the samples until they are solid and label them "Frozen."
2. Allow "Frozen" samples to thaw completely.
3. Shake "Frozen" sample and "Suspect" samples **from the same batch**.
4. Observe "Frozen" and "Suspect" samples side-by-side to compare their **rates of sedimentation** (typically 5–15 minutes).

IF:	THEN:
"Suspect" sediments **SLOWER** than "Frozen"	 USE
"Suspect" sediments at the **SAME RATE** or **FASTER** than "Frozen"	**DO NOT USE!** The vaccine **IS DAMAGED.**

! You must perform the shake test for each separate batch of vaccine !

Supported by the USAID-funded HealthTech program and the Children's Vaccine Program at path

August 2003

ID SHEETS

N°	FREEZER

Brand: Model : Serial N°:

Gross storage volume : litres = icepacks Freezing capacity : kg/24h = icepacks .Holdover time during power cut at 43°C = hours

Icepacks in stock: 0.6 litre □ 0.4 litre □ Other □

Presence of temperature monitoring tools: (mark if present) Date: Thermometer □ Temperatures monitoring sheet □

N°	REFRIGERATOR

Brand: Model : Serial N°:

Net storage volume : litres

Gross storage volume : litres

(only for vaccination campaign)

Holdover time during power cut at 43°C = hours

DRUGS IN STOCK:

Presence of temperature monitoring tools: (mark if present)

Thermometer □ Temperatures monitoring sheet □

StopWatch card or (3M with FreezTag) □

LogTag □

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