PQS Independent type-testing protocol

TITLE: Vaccine freezer or combined vaccine/icepack freezer: compression-cycle

Product verification protocol:	E03/FZ01-VP.1
Applies to specification ref(s):	E03/FZ01.1
Date of origin:	02.08.2007
Date of last revision:	Replaces PIS E3/PROC/3 dated 01.01.1998

Contents:

1. Scope:

This document describes the procedure for verifying the performance of compression type vaccine freezers or vaccine/icepack freezers. A product that passes the relevant tests will be pre-qualified with a specific temperature zone designation. Three temperature zone are described: moderate zone, temperate zone and hot zone.

2. Normative references:

DIN 8985: 1983-05: *Testing the surfaces of installed refrigerators and freezers.*

IEC 60335-1: 2006: *Household and similar electrical appliances - Safety - Part 1: General requirements.*
IEC60335-2-24: 2007 - *Household and similar electrical appliances - Safety - Part 2-24: Particular requirements for refrigerating appliances, ice-cream appliances and ice-makers.*
ISO/IEC 17025: 2000: *General requirements for the competence of testing and calibration laboratories.*
WHO/PQS/E03/FZ01.1: *Performance Specification: Vaccine freezer or combined vaccine/icepack freezer: compression-cycle.*

3. Terms and definitions:

Holdover time: The time in hours during which all points in the vaccine or icepack freezing compartment of the freezer remain below -10°C after the power supply has been disconnected.
Hot zone: Hot zone appliances must operate at a steady +43°C ambient temperature and over a+43°C/+25°C day/night cycling temperature range.
Icepacks: Flat plastic containers, filled with water, conforming to one of the specifications in PQS section E05.
Icepack freezing capacity: The maximum weight of icepacks which can be frozen, in one batch, during a 24 hour freezing cycle. During this period the temperature of the vaccine storage compartment must not exceed -15ºC, except during the actual freezing process when a rise to a maximum of -5°C is permitted.
In writing: means communication by letter, fax or email.
Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.
Manufacturer's gross volume: The manufacturer's stated gross volume or, for purposes of comparison, the internal free volume, including the space occupied by the freezing compartment, and the volume occupied by shelves, but excluding the space taken by the ice-lining or other type of thermal storage, if present.
Moderate zone: Moderate zone appliances must operate at a steady +27°C ambient temperature and over a+27°C/+10°C day/night cycling temperature range.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
Reseller: A commercial entity, licensed to act on behalf of a Legal Manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the Legal Manufacturer.
Temperate zone: Temperate zone appliances must operate at a steady +32°C ambient temperature and over a+32°C/+15°C day/night cycling temperature range.
Vaccine storage capacity: The net capacity in an appliance available for the storage of vaccines. It is measured in litres in the following manner:

- **Freezers:** The vaccine storage compartment is loaded up to the manufacturer's loading markings with boxes measuring 100x100x100 mm or

100x100x50 mm, packed so that there is minimal air space between each column of packets or between the packets and any adjoining wall. The total volume of the boxes, in litres, represents the net volume available for the storage of vaccines.

- **Refrigerators:** The vaccine storage compartment is loaded up to the manufacturer's loading markings with boxes measuring 100x100x100 mm or 100x100x50 mm, packed so that there is a minimum of 15mm air space between each column of packets or between the packets and any adjoining wall. If baskets are provided, the boxes are loaded into the baskets in the same manner, except that they may touch the sides of the basket(s). The total volume of the boxes, in litres, represents the net volume available for the storage of vaccines.

4. Applicability:

Type-testing will be carried out by an independent ISO/IEC 17025 testing laboratory, accredited by WHO.

5. Type-testing procedure:

5.1 *Evidence of conformity assessment:*

Products must carry the CE mark, UL mark and/or equivalent internationally accepted evidence of conformity assessment.

5.2 *Number of samples:*

The Legal Manufacturer or Reseller must supply the testing laboratory with a full duplicate set of the Product Dossier already supplied to WHO in accordance with the requirements of specification clause 7. One sample of the product is required. If more than one version of the product is available (for example, for different climate zones), provide one sample of each version. Ensure that the voltage and frequency rating of the sample(s) is suitable for the country where the test laboratory is located[1].

5.3 *Test procedure:*

5.3.1 Test 1: Type examination:

- **Step 1:** Unpack the product. Using the manufacturer's installation instructions only, set up the system components. Record the process and any problems encountered.
- **Step 2:** Check all samples for similarities between different models[2], dissimilarities between samples of one model, any defects or damage or any problem which make it difficult or impossible to test the appliance.

[1] If there is any doubt that the performance of the product will vary under the other nominal voltage/frequency combinations supplied by the manufacturer, he must be asked to comment in writing.

[2] The purpose of this inspection is to establish whether products offered by competing companies are re-badged versions of an otherwise identical product.

- **Step 3:** Record any differences between the samples ordered and those received.
- **Step 4:** Tabulate the following information for each model submitted for examination. Obtain any additional supporting information required in writing from the Legal Manufacturer or Reseller and attach this information to the report:

  Identification:
  - Code (a unique identifier to be assigned by the testing laboratory);
  - Model;
  - Legal Manufacturer or Reseller;
  - Product type (i.e. vaccine freezer or combination unit);
  - Country of origin;
  - Conformity assessment markings (e.g. CE mark).

  Performance characteristics:
  - Temperature zone rating sticker conforms/does not conform to Annex 1 design.
  - Cycle type conforms/does not conform to specification clause 4.2.2.
  - Voltage and frequency conforms/does not conform to specification clause 4.2.3.
  - Exclusion of areas not suitable for vaccine storage conforms/does not conform to specification clause 4.2.5.
  - Thermometer conforms/does not conform to specification clause 4.2.7.
  - Evaporator configuration conforms/does not conform to specification clause 4.2.11.
  - Lock conforms/does not conform to specification clause 4.2.12.
  - Corrosion resistance conforms/does not conform to specification clause 4.2.13.
  - Electrical safety rating conforms/does not conform to specification clause 4.2.14.
  - Markings conform/do not conform to specification clause 4.2.15.
  - Vaccine storage advice conforms/does not conform to specification clause 4.2.16.

  Environmental requirements:
  - Ambient temperature range during transport and storage conforms/does not conform to specification clause 4.3.1.
  - Ambient humidity range during transport, storage and use conforms/does not conform to specification clause 4.3.2.

  Physical characteristics:
  - Overall dimensions conform/do not conform to specification clause 4.4.1.

  Interface requirements:
  - Voltage stabilizer compatibility conforms/does not conform to specification clause 4.5.1.
  - Power lead conforms/does not conform to specification clause 4.5.2.

  Human factors:
  - General design of the product conforms/does not conform to specification clause 4.6.1.

- Control panel and thermometer conforms/does not conform to specification clause 4.6.2.

Materials and construction:

- Record materials of all major visible components;
- Refrigerant conforms/does not conform to clause 4.7.1.
- Thermal insulation foaming agent conforms/does not conform to specification clause 4.7.2.
- Other restricted materials listed in clause 4.7.3 are/are not present.

Physical data:

- Record major rectangular dimensions in centimetres (± 1.0 cm).
- Record weight in kilograms (± 0.25 kg).
- Record internal volumes of freezer compartment(s) in litres.
- Record estimated vaccine storage capacity in litres;
- Record maximum icepack capacity in kilograms.

Warranty

- Warranty conforms/does not conform to specification clause 4.8.

Instructions:

- Instructions conform/do not conform to specification clause 4.11.

- **Step 5:** Take a three quarter view digital photograph of the appliance with the door open. A 100 x 70 mm should be provided for attachment to the PQS report. Take any other photographs needed to illustrate features of the product in the report.
- **Acceptance criteria:** Inspection indicates full conformity with all major specification requirements.

5.3.2 Test temperatures:

The specific tests listed below apply equally to moderate zone, temperate zone and hot zone appliances. Relevant test chamber temperatures are given in the following format M:<XX°C> for moderate zone; T:<XX°C> for temperate zone and H:<XX°C> for hot zone.

5.3.3 Test 2: Cool-down

- **Step 1:** Set the test chamber temperature to M:+27ºC, T:+32°C, H:+43°C and leave for 48 hours with the appliance empty, the lid or door open and the power supply switched off.
- **Step 2:** Close the lid or door of the freezer, switch the appliance on and leave it to stabilize with the thermostat/fast freeze switch on its maximum setting.
- **Step 3:** Record temperatures every minute for 24 hours. During this period measure the energy consumption and determine the compressor duty cycle. Measure the duty cycle by timing from the end of one cycle to the end of a corresponding cycle approximately 24 hours later. Calculate the percentage 'on' time over this period. Measure electricity consumption over the same time scale.
- **Acceptance criterion:** Stabilized internal temperatures maintained at or below -15ºC.
- **Rejection criterion:** Failure to stabilize at or below -15ºC within the test period.

5.3.4 Test 3: Stable running and power consumption test

- **Step 1:** Set the test chamber temperature to M:+27ºC, T:+32°C, H:+43°C and leave for 48 hours with the appliance empty, the door open and the power supply switched off.
- **Step 2:** Fully load the appliance with simulated vaccine as described in Annex 1.
- **Step 3:** Close the lid or door of the freezer, switch the appliance on and leave it to stabilize with the thermostat/fast freeze switch on its maximum setting.
- **Step 4:** Record temperatures every minute for 24 hours. During this period measure the energy consumption and determine the compressor duty cycle. Measure the duty cycle by timing from the end of one cycle to the end of a corresponding cycle approximately 24 hours later. Calculate the percentage 'on' time over this period. Measure electricity consumption over the same time scale.
- **Step 5:** If the internal temperatures are not correct, adjust the thermostat, if it is possible to do so, and repeat steps 1 to 4. If successful, the newly established setting is referred to as the *revised optimum*. Record all thermostat settings and the outcomes for each setting. Once the *revised optimum* is established DO NOT adjust the thermostat during subsequent tests.
- **Acceptance criteria:** Stabilized internal temperatures at or below -15ºC. Power consumption to be reported.
- **Rejection criteria:** Failure to stabilize at or below -15ºC within the test period.

5.3.5 Test 4: Icepack freezing capacity (combination units only)

- **Step 1:** Stabilize 12 no. 0.6 kg icepacks at M:+27ºC, T:+32°C, H:+43°C .
- **Step 2:** Load the icepacks into the freezer compartment, if possible in a row and with the edges perpendicular to the evaporator surface. Install the freezer thermocouples (minimum 8 no.), centred as uniformly as possible between the loaded icepacks. The minimum distance between a thermocouple and the lid/door, wall or evaporator should be 30mm.
- **Step 3:** Turn on the fast-freeze switch (if present). DO NOT adjust the thermostat.
- **Step 4:** Record icepack and vaccine load temperatures every minute for the following 24 hours.
- **Step 5:** As soon as the icepacks are frozen (to -3ºC or below) AND the vaccine load has returned to -15°C or below, the icepacks can be removed. Check that the vaccine load has stayed below -5°C throughout the test period. Check that the icepacks have been fully frozen within the 24 hour test period.
- **Step 6:** Repeat steps 1 to 5 introducing additional icepacks up to the point when one or more of the following conditions occurs:
  - One or more of the icepacks does not fully freeze within the 24 hour period;
  - The temperature of the vaccine load exceeds -5°C during the freezing process;
  - The temperature of the vaccine load does not return to -15°C or below by the end of the 24 hr test period.

  Establish and record the maximum weight of icepacks that can be frozen whilst still meeting the requirements of specification clause 4.2.3.

- **Acceptance criteria:** A minimum of 7.2 kg of icepacks must be frozen within 24 hours. The vaccine storage temperature must return to -15°C or below by the end of the 24 hr cycle and the vaccine storage temperature must not exceed -5ºC at any time during the test period.
- **Rejection criterion:** Failure to meet one or more of the acceptance criteria.

5.3.6 Test 5: Holdover time

- **Step 1:** Fully load the appliance with simulated vaccine as described in clause 5.3.4. Ensure that the icepack compartment (if present) is empty.
- **Step 2:** Switch the appliance on and allow the temperature of the vaccine load to stabilize for 48 hrs.
- **Step 3:** Switch off the appliance at the moment when the thermostat switches on the compressor.
- **Step 4:** Monitor the temperature of the vaccine load at one minute intervals. At the moment when the warmest point in the load exceeds -10ºC, record the elapsed time since switch off.
- **Acceptance criterion:** No standard set. Performance data will be published in the PQS data sheet.

5.3.7 Test 6: Day/night test

- **Step 1:** Stabilize the test chamber at M:+27ºC, T:+32°C, H:+43°C. Fully load the appliance with simulated vaccine as described in clause 5.3.4. Ensure that the icepack compartment (if present) is empty.
- **Step 2:** Switch the appliance on and allow the temperature of the vaccine load to stabilize. Allow to run for a further 24 hrs.
- **Step 3:** Over a 3-hour period reduce the temperature of the test chamber to M:+10ºC, T:+15ºC, H:+25ºC. Hold this temperature for 9 hours. Raise the temperature to M:+27ºC, T:+32°C, H:+43°C over a 3-hour period. Hold at M:+27ºC, T:+32°C, H:+43°C for a further 9 hours. Reduce again to M:+10ºC, T:+15ºC, H:+25ºC again over a further 3 hr period. Repeat this simulated day/night cycle five times. Record the vaccine load temperature every minute.
- **Step 4:** Review the data and establish the highest and lowest temperatures recorded during the test.
- **Acceptance criterion:** Vaccine load temperatures must remain at or below -15ºC throughout the test.
- **Rejection criterion:** Vaccine load temperature exceeds -5 ºC

5.3.8 Test 7: Maximum icepack freezing load

- **Step 1:** Set the test chamber temperature to M:+27ºC, T:+32°C, H:+43°C and with the appliance empty, the power supply switched on and the freezer temperature between -15ºC and -25ºC. Stabilize the icepacks to be used for the test at M:+27ºC, T:+32°C, H:+43°C.
- **Step 2:** Fill the freezing compartment, including the fast-freeze zone, with icepacks at M:+27ºC, T:+32°C, H:+43°C with a combined volume of one third of the manufacturer's stated gross volume[3]. Instrument the icepack load in

[3] The volume of icepacks should be calculated on the basis of the nominal unit volume of the icepacks used (e.g. 0.6 litre) NOT on the basis of their stacked volume.

accordance with Figures 1 and 2 for E03/FZ-01 under points 7 to 10 and 5 in Annex 2.

- **Step 3:** Turn on the fast-freeze switch (if present). DO NOT adjust the thermostat.
- **Step 4:** Monitor internal and icepack temperatures every minute for 24 hours. The load is assumed to be completely frozen when the temperature of the warmest icepack reaches -3ºC. Next introduce additional icepacks up to the point when one of the icepacks does not fully freeze within the 24 hour period;
- **Step 5:** Record the weight of icepacks frozen within the 24 hour test period
- **Acceptance criterion:** No standard set. Performance data will be published on the PQS data sheet.

5.3.9 Test 8: Compressor starting test

- **Step 1:** Empty the freezer.
- **Step 2:** Switch on the appliance using a starting voltage 20% lower than the nominal voltage of the compressor.
- **Step 3:** Repeat Step 2 ten times from cold with the compressor at M:+27ºC, T:+32°C, H:+43°C.
- **Step 4:** Repeat Step 2 ten times with the compressor at its normal stable running temperature.
- **Step 5:** Reduce the voltage to -22% of the nominal voltage, repeating steps 2 to 4 for each voltage.
- **Step 6:** If there is a test failure at or before the -22% voltage test, establish the likely cause of the problem and include the diagnosis in the test report.
- **Acceptance criterion:** Ten out of ten starts must be successful in both cold start and hot start tests at a minimum of 22% below the manufacturer's nominal voltage.
- **Rejection criterion:** One or more start failures.

5.4 *Test criteria for qualification:*

A final report must be issued after all testing is complete. The report of the tests must contain the following data and analyses:

- **Summary:** Conclusions and recommendations, including confirmation of the temperature zone(s) for which the product is suitable.
- **Test 1:** Comments on samples received, tabulated data on the type-examination test and relevant photographs.
- **Test 2:** Results of cool-down test, including temperature graphs.
- **Test 3:** Results of stable running and consumption test, including temperature graphs.
- **Test 4:** Results of icepack freezing capacity test (if relevant), including temperature graphs.
- **Test 5:** Results of holdover time test, including temperature graphs.
- **Test 6:** Results of day/night test, including temperature graphs.
- **Test 7:** Results of maximum icepack freezing load test, including temperature graphs.
- **Test 8:** Results of compressor starting test.

- **Annexes:** Description of the test apparatus. Test chamber temperature records. Copy of reference thermometer calibration certificate(s). Diagrams showing the location and identification codes for temperature sensors, clearly distinguishing between sensors measuring vaccine, icepack, freezer and evaporator temperatures. Additional supporting documentation requested and received from the Legal Manufacturer or Reseller during the course of the type-testing.

6. Quality control checklist:

6.1 *Quality control standards:*
All testing and reporting must be carried out in accordance with the requirements of ISO 17025:2005 or later edition.

6.2 *Quality control checklist:*
An on-site inspection of the manufacturing plant is not required.

6.3 *Quality control evaluation:*
Not required.

7. Pre-qualification evaluation:

A product will qualify for inclusion on the register of PQS pre-qualified vaccine/icepack freezer equipment in accordance with WHO procedures provided the final report indicates full conformity with the requirements of specification **E03/FZ1.**

8. Modified products:

The legal manufacturer or reseller must notify WHO in writing of any changes which affect the performance of the product. WHO will carry out a desk evaluation of the reported change(s). If any change is deemed adversely to affect the performance of the product, WHO may request full or partial re-verification based on the test procedures described in this document.

Annex 1 – General test conditions

The following conditions are applicable to all refrigerator and freezer tests.

Test conditions:

- Carry out tests in a test chamber in which temperatures can be controlled to ±1ºC and humidity within the range of 45% to 75% unless otherwise stated below.
- Maximum room temperatures of +27ºC, +32ºC and +43ºC are required for the tests.
- Temperatures within the appliance must be continuously monitored to an accuracy of ± 0.5ºC without the presence of the sensors influencing the test in any way. Thermocouples that are sealed within the appliance are most commonly used. Up to 15 simultaneous temperature measurements may be required for a single appliance. The suggested temperature sensor locations are shown in Annex 2.
- Position the test appliance in the test chamber with its back face 200mm clear of one of the chamber walls. Ensure that it is accurately levelled.

Stabilization times:

Before measuring the performance of a refrigerator or freezer under normal running conditions, temperature conditions inside the appliance must be stable. This is normally assumed to exist when either:

- The thermostat has been cycling for 24 hours, or
- The temperature at each of the thermocouple points in the appliance varies by less than 2ºC over 24 hours.

Loading:

Appliances are tested in both the empty and the loaded condition. Tests which call for a vaccine load require cardboard boxes 100 x 100 x 100 mm and 100 x 100 x 50 mm containing empty glass vials or bottles such that the gross weight of the load is equivalent to 0.35 to 0.45 kg per litre of boxes.

The appliance should be filled up to any maximum loading line recommended by the manufacturer. The load must not be placed in the fast freeze compartments of freezers. If baskets and shelves are supplied by the manufacturer, these should be used.

- *Freezers:* The dummy vaccine load must be packed so that the smallest possible air spaces are left between the boxes, between the boxes and the internal walls of the appliance or between the boxes and the internal face of the loading basket(s) - if supplied.
- *Refrigerators:* The dummy vaccine load must be packed leaving a continuous 15mm air space between each column of boxes and between the outermost boxes and the adjoining walls of the refrigerator. If loading baskets are supplied, these should be filled in the same manner, but the outermost boxes may be tight up against the internal faces of the basket(s).

The total volume of vaccine which can be stored in this way represents the vaccine storage capacity to be used in the tests. In all cases, the volume and distribution of the vaccine load should be recorded.

Tests which require icepacks must use 0.6 litre icepacks conforming to Specification E05/IP-01 or 0.4 litre icepacks conforming to specification E05/IP-02.

Recording temperatures

Temperatures are recorded at various points within an appliance to monitor the temperature of the load, or the internal temperatures of the appliance when empty. Readings must be taken once per minute.

In general, temperatures at the centre of the vaccine load or empty cabinet are recorded together with any positions which are likely to experience extremes of temperature. Such positions might be near door seals, or where air circulation is restricted by the appliance design. In addition, other positions are also monitored so that an overall picture of the temperature distribution can be obtained – see Annex 2.

Where applicable, the following points should also be monitored:

- Surface temperature of evaporator plates;
- Flue temperature;
- Condenser fins or outer skin temperatures.

The position of sensors must never be altered during the stable running tests.

Multi-fuel and multi-function appliances

In cases where an appliance can use more than one fuel or power source (typically absorption refrigerators) the tests should start on electrical power before moving to another option.

In the case of appliances which can be run either as a freezer or as a refrigerator, the first set of tests should test the refrigerator function and the second set should test the freezer function. Dual compressor systems should be tested with both compressors on as this is typical of actual use.

Multi-fuel, multi-function equipment will be lengthy and costly to test, so a decision on which options should be tested will be made by WHO on a case by case basis.

Annex 2 – Temperature sensor positions

Figure 1: Chest freezers

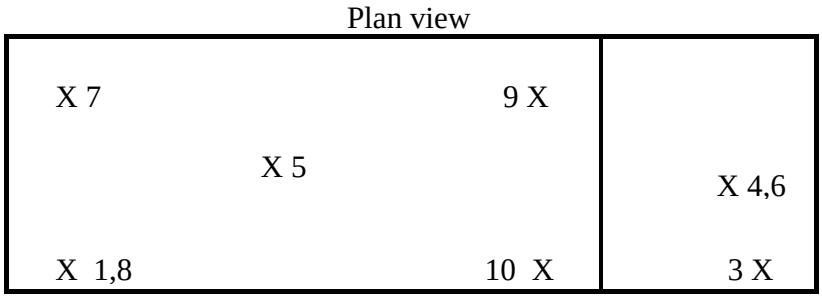


Figure 2: Chest freezers

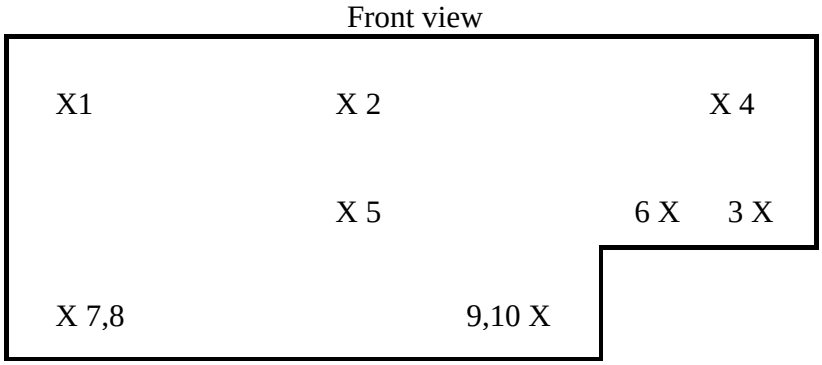
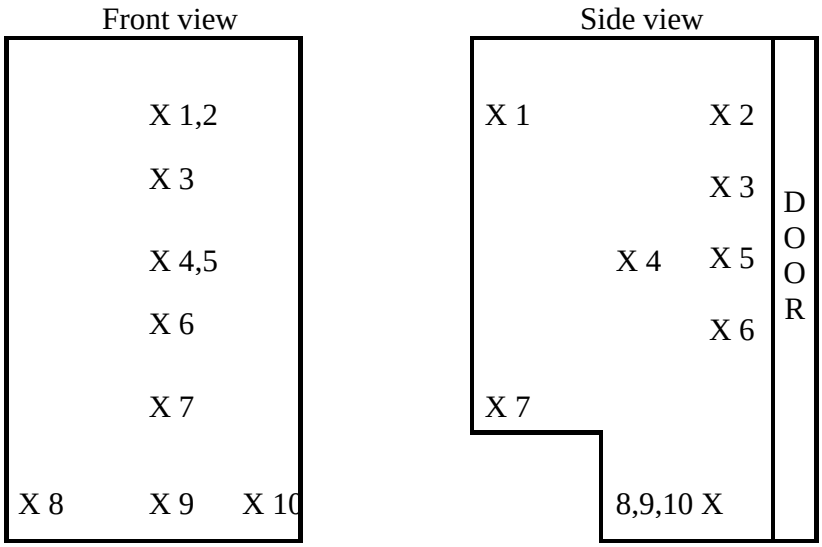


Figure 3: Icepack fast freezers



Revision history:			
Date	Change summary	Reason for change	Approved
08.03.2007	General edit	Final revisions to PQS format.	UK
23.05.2007	UK, SMc comments incorporated. Definition of 'areas not suitable for vaccine storage' removed.		UK