TITLE: Refrigerated vehicles – Type-examination protocol	
Verification protocol reference:	WHO/PQS/E002/RV01-VP.3
Specification reference:	E002/RV01.3
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Contents

1. Scope

This document described the process for verifying the performance of refrigerated vehicles. It should be read in conjunction with the PQS performance specification **WHO/PQS/E002/1.2** for refrigerated vehicles which describes the performance requirements for all sizes of refrigerated vehicles suitable for transporting and/or storing vaccine. The performance specification also lists options and variations that the procurement agent or end user can select in addition to the standard specification.

2. Terms and definitions

Acceptable temperature range: The acceptable temperature range for storing vaccine is +2°C to +8°C. However, transient excursions outside this range will be tolerated, within the following limits:
• No excursion must exceed +20°C (± 0.5°C) for any amount of time,
• No excursion must drop below -0.5°C for any amount of time,
• No excursion must drop below 0°C for longer than 1 hour, and
• Following an excursion below 0°C, the appliance must return to safe operating temperature (i.e. consistently between +2°C and +8°C) within two hours. This duration will be measured from the moment the temperature drops below 0°C and up until it returns to +2°C.
Climatic classes: Hot Zone: 0°C to 50°C; Moderate Zone: 0°C to 32°C; Temperate Zone: 0°C to 27°C and Cold Zone -20°C to 32°C.
Cold climate extreme temperature prevention: Any mechanism which prevents the temperature inside a refrigerated vehicle from falling below than +2°C under low ambient temperature conditions, down to the temperature specified by the employer at the time of procurement, subject to a lowest temperature of -20°C ambient.
Cold zone (refrigerated vehicles): Cold zone units must maintain the acceptable temperature range while operating at any ambient temperature from +32°C to -20°C.
Employer: The organization that contracts with the legal manufacturer or reseller who will supply the vehicle and maintenance advisory services described in the performance specification: WHO/PQS/E002/RV01.1.
Evaluator: An individual or organization (including a testing laboratory) responsible for evaluating the suitability of the components and services described in this specification for inclusion in the register of PQS pre-qualified products.
Hot zone (refrigerated vehicles): Hot zone units must maintain the acceptable temperature range while operating at any ambient temperature from +50°C to 0°C.
In writing: communication by letter, fax or email.
Kigali Amendment: The Kigali Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer entered into force on 1 January 2019, following ratification by 65 countries. The UN Environment Programme (UNEP, or UN Environment) announced the entry into force to help reduce the production of hydrofluorocarbons (HFCs) and potential greenhouse gases (GHGs).
Kyoto Protocol: The Kyoto Protocol is an international treaty which extends the 1992 United Nations Framework Convention on Climate Change that commits state parties to reduce greenhouse gas emissions. It was adopted in Kyoto, Japan, on 11 December 1997 and entered into force on 16 February 2005.
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 the person's own name, regardless of whether these operations are carried out by that person or on that person's behalf by a third party.
Maintenance contractor: A person or organization contracted by the employer to maintain the installation, devices, and/or appliances.
Moderate zone (refrigerated vehicles): Moderate zone units must maintain the acceptable temperature range while operating at any ambient temperature from +32°C to 0°C.
Montreal Protocol: The Montreal Protocol, finalized in 1987, is a global agreement to protect the stratospheric ozone layer by phasing out the production and consumption of ozone-depleting substances (ODS).
Quality assurance (QA) assessor**:** the person or entity appointed by the employer to assess the quality and suitability of manufacturing sites and/or candidate approved

installers.
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 (refrigerated vehicles): Temperate zone units must maintain the acceptable temperature range while operating at any ambient temperature from +27°C to 0°C.
TTSPP: Time and temperature–sensitive pharmaceutical products.
User: The person responsible for the day to day operation and temperature monitoring of the vehicle.

3. Normative references

(Use most recent version of each reference)

ATP (agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be used for such Carriage).
PPECB Refrigerated Road Motor Transport protocol. Revision 2 (2020-03-28)
Montreal Protocol: agreement on ozone depleting refrigerant gases.
Kigali Amendment: to the Montreal Protocol on Substances that Deplete the Ozone Layer
Kyoto Protocol: an international treaty which extends the 1992 United Nations Framework Convention on Climate change.
EN 17066-1: 2019 - Insulated means of transport for temperature sensitive goods Insulated means of transport for temperature sensitive goods Part 1 - Requirements and testing.
IEC 60068-3-11:2007 Environmental testing - Part 3-11: Supporting documentation and guidance - Calculation of uncertainty of conditions in climatic test chambers.
IEC 62552-1: Household refrigerating appliances - Characteristics and test methods - Part 1: General requirements.
ISO 9001: Quality Management Systems – Requirements.
ISO 14001: Environmental management systems - Requirements with guidance for use.
ISO 20282-1:2006 Ease of operation of everyday products – Part 1: Context of use and user characteristics.
EN 12830: 2018 - Temperature recorders for the transport, storage and distribution.
BS EN 3 Parts 1 to 6, or equivalent: portable fire extinguishers.
NFPA 1802: Standard on Personal Portable (Hand-Held) Two-Way Radio Communications Devices.
Qualification of temperature-controlled road vehicles Technical supplement to WHO Technical Report Series, No. 961, 2011. Annex 9: Model guidance for the storage and transport of time and temperature–sensitive pharmaceutical products (TTSPPs).
WHO/PQS/E006/TR03.2: Programmable electronic temperature and event logger systems with integral alarm and auto-dialer options.
WHO/PQS/E006/TR03-VP2.2: Programmable electronic temperature and event logger systems with integral alarm and auto-dialer options – Quality Assurance protocol.
Directive 2002/96/EC of the European Parliament and of the Council Directive 2004/108/EC of the European Parliament and of the Council.
ISO/DIS 14993(en) Corrosion of metals and alloys — accelerated testing involving cyclic exposure to salt mist, dry and wet conditions.
ISO 11997-1:2017 Paints and varnishes — Determination of resistance to cyclic corrosion conditions — Part 1: Wet (salt fog)/dry/humid.

ISO 8002:1986(en) Mechanical vibrations — Land vehicles — Method for reporting measured data.
IEC 61000-6-1:2016 Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity standard for residential, commercial and light-industrial environments.
IEC 61000-6-3:2006+AMD1:2010 CSV Consolidated version. Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for residential, commercial and light-industrial environments.

4. Applicability

The type-examination to be carried out by an independent evaluator, appointed by WHO ideally at the manufacturing site or, at another agreed location. The extent of the geographical limits of any grant of prequalification status will be reviewed and decided upon by WHO.

5. Specification evaluation

5.1 Type-examination procedure

- **Step 1:** Check sample for any defects or damage.
- **Step 2:** Record any differences between the sample requested and that received.
- **Step 3:** Check and record the vehicle meets the requirements for all parts of the PQS Performance specification – Refrigerated vehicles **E002/RV01.2** Section 4. For each sub-section record detailed comments, compliance, non-compliance and recommendations. Where a measured specification is required, e.g. clause 4.2.8 insulation, the measurement(s) must be stated, not just “pass” or “fail”.
- **Step 4:** Take detailed photographs of the vehicle exterior, the interior of the refrigerated body and the cab interior. Also take detailed photos of the cooling/heating units, including the temperature control system(s).
- **Step 5:** Obtain any additional supporting information required in writing from the legal manufacturer or reseller and attach this information to the report.

Acceptance criteria: Inspection indicates full conformity with specification requirements, subject to acceptable restrictions on temperature zones and region(s).

5.2 Calculating required cooling capacity

Calculate the required cooling capacity for the refrigerated vehicle. This can be done either via the method shown in Annex 1 of this protocol, or in accordance with **EN 17066** methodology, or any other demonstrably equivalent method. Whichever method is selected for this calculation, a full breakdown of the calculation must be shown to PQS.

5.3 Performance test procedure

Whichever test procedure is used, the following **acceptance criteria** must be demonstrated:

- The temperature distribution within the payload area of the temperature-controlled compartment is maintained within the range specified for the products being transported (e.g. +2.0°C to +8.0°C). The qualification procedure must be able to assess actual product temperatures for commonly used load layouts. Qualification

should be carried out at the ambient temperature extremes anticipated during the proposed climate zone.

- Time taken for temperatures to exceed the designated maximum or minimum in the event that the temperature-controlling unit fails. Similar tests should be used to validate the anticipated door-opening times that will occur during deliveries.

The above acceptance criteria may be demonstrated using the test procedure clause 5.3.1, clause 5.3.2 and clause 5.3.3 below or by an internationally accepted test protocol e.g. ATP testing.

5.3.1 General test conditions for E002/RV01-VP.2 testing

Temperature sensor data to be recorded every minute in accordance with **IEC 62552** Clause A.2.6.
Temperature reading uncertainty[1] no greater than ±0.5°C.
The heater power value to be recorded every minute.
The heater power uncertainty no greater than 1.0 % of the reading.

5.3.1.1 Ambient temperature

The vehicle should be housed in a warehouse or other large building where the ambient temperature and humidity can be expected to not change significantly for the duration of the test. Mean ambient temperature must be within ±1°C of the test ambient with all logged temperatures to be within ±2°C of the test ambient. The spatial average ambient temperature to be recorded every minute. Maximum, mean and minimum ambient temperatures to be declared for the test period.

External temperature sensors to have brass-barrel terminations with a thermal response time no greater than 10 s in accordance with **IEC 62552-1** clause A.2.7.

There should be at least 6 external sensors free from influence of generated heat e.g. not in direct sunlight and away from any heat generated by the engine or from air blowing from the refrigerated unit. These should be centred 10 cm from the external surface of the cold storage wall. For large external surfaces, there should be at least 2 external temperature sensors.

5.3.1.2 Heat and exhaust fumes

Provision must be made for the exhaust fumes of the vehicle engine or its own separate generator to be vented outside the building. Heat from the vehicle engine or generator should be vented to help avoid influence on the ambient test temperature.

5.3.1.3 Internal temperatures

Internal temperature sensors to have brass-barrel terminations in accordance with **IEC 62552-1** clause A.2.6 with a thermal response time no greater than 10 s in accordance with **IEC 62552-1** clause A.2.7, and placed in locations most vulnerable to temperature excursions. These locations may include the corners, places near

[1]Temperature uncertainty encapsulates the whole data recording system from the tip of the sensor to recorded data.

door(s), and weak locations where heat ingress may be expected, e.g. near an external compressor. Taking into account the size of the cold storage area, there should be at least 14 temperature sensors including locations where warmest and coldest temperatures might be expected (see Annex 2) within the parameters of vaccine loading space. i.e. within vaccine load limits and not near circulation fans or space necessary to be kept free for optimum cooling or defrosting[2].

5.3.1.4 Movable partitions

For refrigerated bodies with movable partitions, the partition must be adjusted to achieve the maximum vaccine load space.

5.3.1.5 Internal loading

Internal sensors to be suspended using material that has low internal mass. Sensors near a strong airflow must be shielded so a true temperature can be recorded i.e. to represent the thermal of a vaccine vial inside primary packaging.

An empty load with a number of brass-barrel temperature sensors will simulate a worst-case scenario where the small thermal mass may be subject to over-cooling in a warm ambient. (It will not be possible to simulate the other worst-case scenario where a large thermal mass which needs to be kept warm in a cold ambient.)

Near the centre of the internal storage space, install electrical heater(s) with a heating power at least the equivalent to the cooling capacity calculated in Annex 2.

The entry point(s) for any wiring for temperature sensors or heater(s) etc. must be carefully sealed to minimize exchange of air between inside and outside the closed compartment.

5.3.2 Test 1: Evaluation of the cooling capacity

(This test measures whether the cooling system has the cooling capacity as calculated in Section 5.2.)

- **Step 1:** Stabilize the whole vehicle at a chosen test ambient between 20°C and 35°C in accordance with the requirements of clause 6.3.1.1 for at least 12 hours.
- **Step 2:** Cool the interior to the coldest or lowest possible thermostat setting.
- **Step 3:** With the cooling system on this setting, switch on the test heater(s) and adjust the test heater to achieve an inside temperature which matches the outside ambient temperature.
- **Step 4:** After interior temperatures have reached stability, run the test for at least three hours so that several cooling cycles will be demonstrated.

N.B. It is possible that the cooling system will be on continuously but if cycling occurs, at least five cooling cycles to be exhibited in the results.

[2] Note: The limits of vaccine loading must be clearly indicated inside the storage area facilitate correct loading.

Ambient temperature, internal temperature and heater power output to be displayed graphically together on the same axis.

Acceptance criteria: The measured cooling capacity must be at least as good as the theoretical cooling capacity calculated in Section 5.2.

5.3.3 Test 2: Evaluation of climate zone and set point

- **Step 1:** Remove the heater set-up from Test 1. Allow the interior of the body to cool for at least 12 hours.
- **Step 2:** Adjust the ambient temperature to the warmest ambient for the declared climate zone.
- **Step 3:** Adjust the cooling system's set point to +5°C. When a steady state has been achieved, run the test for three hours at the warmest ambient.
- **Step 4:** Ramp down the ambient temperature to the coldest ambient for the declared climate zone at a rate of six degrees per hour.
- **Step 5:** After reaching the coldest ambient, immediately test for three hours. Do not adjust the set point.
- **Step 6:** Report the maximum, minimum and mean ambient and internal temperatures over the whole test period from the warm ambient, ramping down and then the cold ambient. Ambient temperature, all internal temperatures and power consumption to be displayed graphically together on the same axis.

Acceptance criteria: All measured internal temperatures must be within the acceptable temperature range of [2, 8]°C as defined in Section 2 of this verification protocol.

5.4 Test Criteria for qualification

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

- **Summary:** Conclusions and recommendations.
- **Scope:** Review of samples and construction options included in the type examination exercise, including a list of any that is specifically excluded.
- **Compliance checklist:** Showing the vehicle meets the requirements stated in PQS specification reference **E002/RV01.2**. Where a measured specification is required, the measurement(s) must be stated, not just "pass" or "fail".
- All testing must be carried out in accordance with the requirements of the latest edition of **ISO 17025**.
- All test results must demonstrate that the temperature distribution within the vaccine storage area of the temperature-controlled compartment is maintained within the acceptable temperature range including permitted deviations as defined in Section 2 of this verification protocol. Key components must carry the CE mark and or other internationally accepted evidence of conformity assessment.
- **Annexes:** Additional supporting documentation requested and received from the legal manufactures or supplier during the course of the type-

examination. This must include a copy of the applicant's current **ISO 9001** certificate, a copy of the insulated body's ATP type test approval if applicable, a copy of relevant CE certification or other conformity assessment certificates and, where applicable, a copy of the applicant's current **ISO 14001** certificate.

6. Quality control checklist

6.1 Quality control standards

All testing and reporting must be carried out in accordance with the requirements of the latest edition of **ISO 17025**.

6.2 Quality control checklist

An on-site inspection of the manufacturing plant may be required.

7. Prequalification evaluation

An applicant company can apply for inclusion on the register of PQS prequalified refrigerated vehicle suppliers in accordance with WHO procedures as long as the dossier submission provides evidence that the refrigerated vehicle supplied by the company are likely to be able to achieve full conformity with the requirements of the PQS performance specification **E002/RV01.2**.

Prequalification can be acceptable if a company proposes supplying temperate zone equipment to temperate and moderate zone countries. If a hot zone area or country is included in the specified region, this hot zone area or country must be excluded from the prequalification listing for which a separate prequalification must be sought**.**

Although an on-site inspection of the manufacturing plant is not mandatory, the type examination must take place at a location where full-scale components can be inspected.

Demonstration samples must be made available for inspection, as follows:

- Vehicles, bodies and refrigeration unit samples showing insulation, finishes, joint construction, assembly details,
- Sample refrigeration monitoring and control systems,
- Examples and full technical specifications of the refrigeration units offered,
- Examples of instruction and handbook documents in a UN language[3] which the evaluator can understand,
- Digital images of for inclusion in the PQS data sheet, and
- Draft PQS data sheet.

8. Modified vehicles

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 type-examination

[3] Arabic, English, French, Mandarin or Spanish.

procedures described in this document.

Annex 1: Theoretical cooling capacity calculation

Cooling Capacity with examplar calculation:

Transmission load (External heat ingress) $Q = K \times A \times (Ta - T\,i)\ 24 / 1000$

Transmission load	Q (ext) =	11.9808 kWh/day	
Where			
Insulation K value	K =	0.4 $W/m^2/°C$	
Surface area	A =	48 m^2	For a truck with cooling unit dims of 5 x 2 x 2 metres
Ambient air temp	T_a =	30 °C	(See tolerance factors below.)
Internal air temp	T_i =	4 °C	
Floor temp	T_f =	10 °C	

If the floor has a different K-value, then a separate Q will need to be calculated for the floor and added to the walls and roof.

If the vaccine Has a temperature of 4°C, then the product load will be zero when transferring from WICR to R Truck.
However, it's likely that vaccine will have warmed for a short time when transferring and therefore needs some cooling.
Difficult to estimate the total mass of the vaccine load to be cooled, therefore calculation is per kg.

Product load vaccine temp	T_v =	10 °C
(Sensible heat)	Q (load) =	$m * Cp * (T_v - T_i) / 3600$
		6.948333 kWh/day per kilogram since we don't know the load

(Heat from health worker and lighting is ignored as this should be small compared with the heat ingress from opening doors.)

Heat load from circulation fan motors	Q (fan) =	No. of fans x time (hours) x wattage / 1000
		5.6 kWh/day
Heat load from defrosting evaporator	Q (defrost) =	Heating element power x time-on x no. of cycles per day
		1.875 kWh/day
Heat load from opening doors	Q (doors) =	No. of times door is opened x volume x heat capacity per m^3 x $(T_a - T_i)$
		0.866667 kWh/day (Divided by 3600.)
TOTAL COOLING LOAD	Q (total) =	27.2708 kWh/day (Sum of the above.)
Tolerance factor	TF = 2.25	Tolerance factor is 2.25 for climate zones warmer than 30°C. i.e. multipy the above by 2.25 Tolerance factor is 1.75 for climate zones colder than 30°C.
Cooling load x tolerance factor =		61.3593 kWh/day
Cooling capacity = cooling load / run time (hours)		4.38 kW

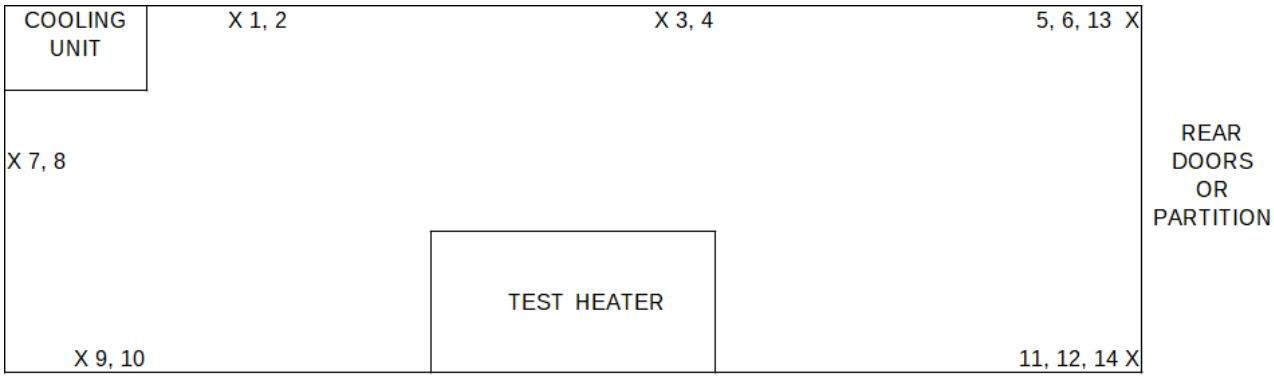
Annex 2: Temperature sensor locations

Example of where temperature sensors may be placed. The warmest and coldest places should be captured. If there are side door(s), temperature sensors must also be placed here.

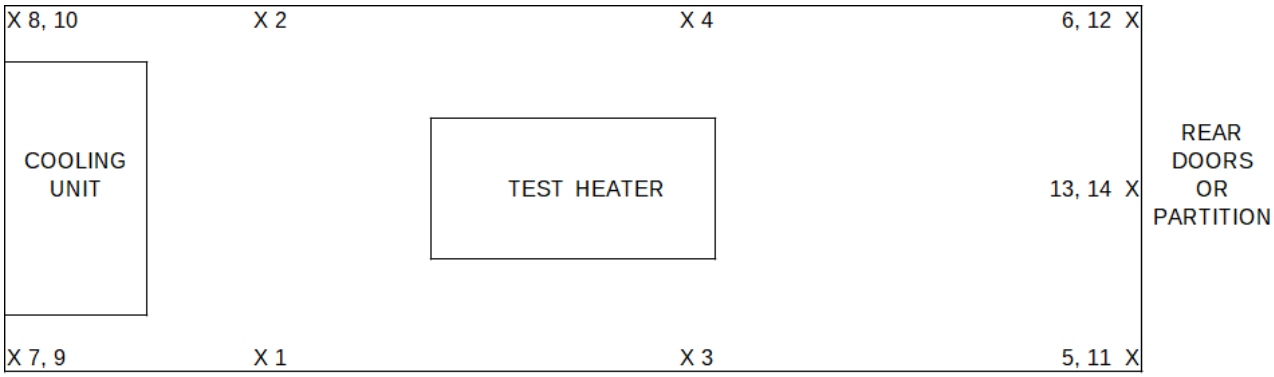
The test report must show the position of the temperature sensors.

Side elevation

Sensor position indicated by ‘x’.



Plan



Notes on sensor positions:

All sensors to be placed 10 cm away from the sides or corners except if there is a load limit is clearly indicated where they should be.10 cm away from the load limit.

Sensors 1, 2, 7 & 8 should be within 10 cm of any load limit. If no load limit indicated, they should be within 10 cm of the cooling unit.

Sensors 13 & 14 to be placed 10 cm away from the central join of the rear double doors or partition.

If there is a side door, additional sensors to be placed top and bottom 10 cm away from the edges of the side door.

Revision history		
Date	**Change & reason summary**	**Approved**
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