PQS performance specification

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1. Scope

Refrigerated vehicles are able to carry a higher volume of heat-sensitive vaccines compared to same-sized vehicles carrying cold boxes. Refrigerated vehicles are specially adapted to carry vaccines and pharmaceuticals at temperatures between 2°C and 8°C can be important elements of cold chain systems.

This document provides a minimum specification for refrigerated vehicles to which clients can select variations and add options. WHO PQS will accept applications for refrigerated vehicles meeting these criteria for prequalification evaluation.

In principle, these specifications apply to vehicles of any size. To calculate the size of vehicle required, reference should be made to the **WHO Vaccine Management Handbook Module VMH-E3-01.**1 including section 3.4.2 “Refrigerated vehicles”. In addition, the type of vaccine, the frequency of re-stocking and the precise method of transportation, e.g. whether on pallets[1], must be considered in order to select appropriate vehicle options. The actual vaccine load capacity depends, not least, on these factors plus configurations of the tertiary packaging within the airspace that can be maintained at correct temperatures (see sections 4.2.14 and 4.2.15).

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 +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 prequalified 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.

[1] Including ISO US or European standard pallet dimensions.

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. Performance

4.1 Vehicle specifications

4.1.1	Base Vehicle:	Chassis Cab with fixed refrigerated body
4.1.2	Drive:	4 x 2; 4 x 4 or 6 x 4
4.1.3	Steering wheel:	Left-hand drive or right-hand drive to be specified by the procurer.
4.1.4	Transmission:	Manual or automatic to be specified by the procurer.
4.1.5	Fuel source:	Diesel or gasoline. (See also clause 4.4.1.)
4.1.6	Emissions:	At least as good as Euro 6 and Euro 6 diesel.

4.1.7 Colour: The cab and body to be white or other surface with very good reflecting properties in the UV, visible and near infra-red wave bands. (See also clause 4.2.3.)

4.1.8 Cab air conditioning.

4.1.9 Front towing hook or loop.

4.1.10 Audible *and* visual warning signals when vehicle is reversing. Audible *and* visual warning signals for refrigerated compartment doors being open and LCU lights left on.

4.1.11 Lockable spare wheel.

4.1.12 Lockable doors to body, lockable fuel cap.

4.1.13 Seat belts to be fitted to all seats.

4.1.14 Cloud-based GPS/satellite vehicle tachograph.

4.1.15 Wired/wireless temperature sensor system with readout of minimum and maximum temperatures in the body visible to the driver with an audible alarm for temperature excursions colder than 2°C and warmer than 8°C.

4.1.16 Temperatures to be electronically recorded and downloadable using devices which meet the requirements of either **EN 13486** or PQS Specification **E006/TR03.2** Programmable remote temperature and event monitoring systems. All temperature data to be captured at least every five minutes.

4.1.17 A temperature controller that allows both auto and manual control of temperature inside the body.

4.1.18 A lockable range of tools, a jack for vehicle, a reflecting warning triangle plus special tools needed for vehicle service including at least one spare wheel.

4.1.19 A portable vehicle fire extinguisher securely mounted in the cab. This should be of a size appropriate for the vehicle and of a type appropriate for the potential type of fire, e.g. a fuel fire, an electrical fire.

4.1.20 Workshop manual and general operating instructions for regular maintenance both for the vehicle and for the chilled section. (See also clause 4.1.24.)

4.1.21 Foldable steps to be provided to rear doors and to side door if fitted.

4.1.22 Programmable vehicle speed limiter.

4.1.23 Front airbags for both driver and passenger sides and side airbags to be fitted for all seats.

4.1.24 Spare parts should be available for at least 10 years from receipt of the vehicle.

4.2 Refrigerated body specifications

4.2.1 Body structure to be rigid and capable of withstanding vibrations and shocks from rough roads while keeping the load fully secured when the vehicle is full and part loaded.

4.2.2 All walls and roof panels - internal and external - sub-frames, main-frames and chassis must be anti-corrosion treated. The corrosion treatment must be able to withstand **ISO 11997-1:2017** Paints and varnishes – Determination of resistance to cyclic corrosion conditions – Part 1: Wet (salt fog)/dry/humid or equivalent.

4.2.3 The external and internal surfaces of the refrigerated body and external surface of the driver's cab must be of a highly reflective finish, e.g. shining white or a more strongly heat-reflecting finish if available. The exterior and interior surfaces must demonstrate very good reflecting properties in the UV, visible and near infra-red wave bands. Bare metal external and internal surfaces are not acceptable. The surfaces must be well-protected and easy to keep clean.

4.2.4 Materials:

4.2.4.1 Hydrocarbon (HC) refrigerants such as R600a or other gases with global warming potential (GWP) ≤ 11 and zero ozone-depletion potential (ODP) are required. Refrigerant: CFC- and HCFC-free to comply with the requirements of the most recent update to the Montreal Protocol. HFC refrigerants should be selected with the lowest practical GWP to meet the aspirations of the Kigali amendment. The suitability of alternative refrigerant gases will continue to be assessed and preference will be given to appliances that use gases with low GWP.

4.2.4.2 Thermal insulation foaming agents: CFC- and HCFC-free and complying with the limitations and deadlines set by the Montreal Protocol on the elimination of ozone-depleting chemicals.

4.2.4.3 Other restricted materials: The product and its constituent components, excluding batteries, must not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

4.2.5 Box body type with rear insulated door(s) complying with Annex 1 Clause 1 I_R specification of the ATP agreement. Door to be full width latched opening with robust hinges, locking and closing mechanisms.

4.2.6 Emergency exit must be possible from the inside of the refrigerated compartment.

4.2.7 Cold strip curtain fitted behind all doors.

4.2.8 No matter which climate zone, the body must be insulated to 0.40 W/m^2K (ATP heavily insulated specification), or better.

4.2.9 Refrigerated body to have at least four drains with U-bends for release of condensate water.

4.2.10 LED interior lighting with switching from all entrance points.

4.2.11 Reinforced non-slip level flooring. In larger vehicles there should be minimal obstructions to allow access for pallets.

4.2.12 Overall vehicle dimensions and wheel-base dimensions to be specified.

4.2.13 Gross external and internal body dimensions to be specified.

4.2.14 Storage dimensions and volume to be specified. The net storage capacity should be calculated in accordance with the Vaccine Management Handbook Section 3.4.3. Vaccine storage must not should include space where it is not possible to store vaccine, e.g. space outside acceptable temperatures range or where free air-flow is required to maintain correct internal temperatures.

4.2.15 For larger vehicles, pallet size(s) with configuration options to be specified.

4.2.16 Space where vaccine should not be stored, e.g. near chiller unit or space outside acceptable temperature range must be indicated by clear load limit markings. If

there are no load limit markings, it will be assumed that everywhere inside the refrigerated body meets the requirements of clause 4.3.1 in this specification.

4.2.17 Maximum load to be specified in kg.

4.2.18 Protection/reinforcement to be provided for nose-mounted or overhead cooling units to help prevent damage from trees or other overhead obstacles. This protection may include snow protection if applicable to the operating environment.

4.2.19 Cargo securing points with load straps and/or load bars to prevent movement including vehicles with racking or shelving.

4.3 Cooling/heating unit specifications

4.3.1 The cooling/heating unit must be capable of maintaining the temperature-controlled compartment between 2°C to 8°C with limited permitted excursions[2] in the extreme ambient temperatures of its climatic zone of use: 0°C to 50°C in a hot zone, 0°C to 32°C in a moderate zone, 0°C to 27°C in a temperate zone, and -20°C to 32°C in a cold zone. Compliance with this requirement must be demonstrated in a test report.

4.3.2 In climate zones warmer than 30°C, the heat extraction capacity must be at least 2.25 times[3] the heat flowing though the insulation and 1.75 times for climate zones colder than 30°C. In cold zones, heating capacity is required to prevent freezing and to maintain 2°C to 8°C.

4.3.3 Power backups, local grid or generator must be available in case of failure of the primary drive for the refrigeration unit. The refrigerated unit must be able to work from at least one of these additional energy sources.

4.3.4 When the loaded vehicle is parked close to a source of mains grid electricity, an extension cable at least 20 m long must be provided to power the refrigeration unit.

4.3.5 The cooling and heating units should be mains voltage tolerant, able to operate within voltages from -22% to +10%. There must be sufficient protection for voltages outside these limits. Also, it should ***not*** be anticipated that a three-phase supply will be available.

4.3.6 In the case that the loaded vehicle is parked without access to mains electricity, provision must be made for non-idle refrigeration to allow the refrigeration unit to run for at least 48 hours.

4.3.7 Automatic and manual defrost options for clearing ice from the evaporator must be provided.

4.3.8 Electrical safety: The legal manufacturer must declare compliance with **IEC 60335-1**, **IEC 60335-2-24** and **IEC 60364-1** or equivalent standard. Evidence for this compliance shall be demonstrated.

4.3.9 EMC compliance: The legal manufacturer must declare compliance with the latest edition of **IEC 61000-6-1** and **IEC 61000-6-3**. Evidence for this compliance shall be demonstrated.

[2] See acceptable temperature range defined in clause 3 of this specification

[3] In accordance with ATP recommendation.

4.3.10 The legal manufacturer must declare compliance that all internal and external components of the refrigerated body are protected against corrosion as appropriate to **EN ISO 6270-1 / ASTM D2247 / EN 13523-26, EN ISO 6270-2 / EN 13523-25, ISO 6272 / EN 13523-**5 and **ISO 2409: 2013**. Evidence for this compliance shall be demonstrated.

4.3.11 Refrigeration spare parts should be available for at least 10 years from receipt of the vehicle.

4.4 Optional variations

4.4.1 Fuel source: LPG or other agreed fuel. Also, fuel combined with a solar array to charge “overnight batteries” for example.

4.4.2 Electric winch at the front of the vehicle.

4.4.3 Commonly used vehicle spare parts e.g. lightbulbs, tyre valves to be provided.

4.4.4 Fixed ladder to access the refrigerating unit of larger vehicles.

4.4.5 A transverse movable insulated partition to facilitate transit of non-cooled items, e.g. syringes. A refrigerated body with a partition should have a side door to enable easier refrigerated item access.

4.4.6 Side door access, particularly for longer vehicles.

4.4.7 Racking or shelving.

4.4.8 Roll cages with tail lift for larger vehicles.

4.5 Warranty

The vehicle must be covered by a minimum one-year replacement warranty from receipt of vehicle in the event of any component failure arising from defective design, materials or workmanship.

The refrigerated body and cooling/heating unit are to be covered by a minimum one-year replacement warranty from receipt of vehicle in the event of any component failure arising from defective design, materials or workmanship.

4.6 Service provision

To be negotiated on procurement.

4.7 Disposal and recycling

The manufacturer must provide information to the buyer on all materials contained within the system with instructions for resource recovery/recycling and/or environmentally safe disposal. For the European Union, WEEE compliance in accordance with **European Union Directive 2002/96/EC** is mandatory. For the rest of the world, compliance to **IECQ 080000 HSPM is** required.

4.8 Instructions

User, maintenance and safety instructions must be available in Arabic, Mandarin Chinese, English, French, Russian and Spanish. The instructions are to be written for users and repair technicians and are to cover the following topics:

- Procedures after initial delivery of vehicle.
- Procedures before every use of vehicle including establish correct function and correct internal temperatures before loading with vaccine.
- Operator safety and PSE.
- Vehicle operation instructions.
- Refrigerated body and cooling/heating unit operation instructions.
- Procedures for correct loading.
- Temperature verification procedures.
- Interpretation of indicator lamps or LEDs.
- Routine maintenance tasks.
- Diagnostic and repair procedures, including replacement of accessible fuses.
- Itemised list of common spare parts for the first 100 000 km including part numbers.
- End-of-life resource recovery and recycling procedures.

4.9 Training

Manufacturer and client to agree training for vehicle operators and maintenance technicians. This training must include:

- Operator safety and PSE.
- Procedures before every use of vehicle including establish correct function and correct internal temperatures before loading with vaccine.
- Procedures for correct loading.
- Vehicle operation instructions.
- Refrigerated body and cooling/heating unit operation instructions.
- Maintenance of the vehicle including daily checks.
- Maintenance of the chilled compartment including daily checks.
- Cleaning of the chilled compartment.
- Cleaning of the whole vehicle.
- Cleaning of any special components e.g. solar array.
- Checking the chilled compartment temperature data (perhaps from a RTMD) on a daily basis.

4.10 Verification

In accordance with PQS Verification protocol **E002/RV01-VP.2.**

5. Packaging

Materials used for packaging the finished product are to be free of ozone-depleting compounds as defined in the Montreal Protocol.

6. On-site installation

Not applicable.

7. Product dossier

The legal manufacturer or reseller is to provide WHO with a prequalification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product type.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- Detailed photographs of the vehicle exterior, the interior of the refrigerated body and of the cooling/heating units.
- Certified copies of all type-approvals obtained for the product, including CE marking and the like.
- Certified copies of the legal manufacturer's **ISO 9001** quality system certification.
- Certified copies of the insulated body's ATP type test approval or any equivalent type test.
- Certified copies of the refrigerating unit's ATP type test approval or any equivalent type test.
- Test report according to **WHO/PQS/E002/RV01-VP.2**.
- Certified copies of the legal manufacturer's **ISO 14001** certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however, preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- Indicative cost of the product per unit, EXW (Incoterms 2010).

8. Maintenance

Maintenance to be carried out by the end-user and/or his agents according to manufacturer's instructions and contractual agreement.

9. Change notification

The legal manufacturer or reseller is required to advise WHO in writing of all changes which may affect the performance of the product after PQS prequalification has taken place.

10. Defect reporting

The legal manufacturer or reseller is required to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events. If requested to do so by WHO/UNICEF, the manufacturer is to submit a report to WHO/UNICEF stating the number of affected systems and the number of component repairs/replacements provided, together with copies of any associated field reports.

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