



**TITLE: Refrigerated vehicles – Type-examination protocol**

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**1. Scope**

This document is used for qualifying suppliers of refrigerate vehicles.

It should be read in conjunction with the PQS Performance Specification<sup>1</sup> for refrigerated vehicles which describes the performance requirements for all sizes of refrigerated vehicles suitable for transporting and storing vaccines. The document also lists options and variations that the client can select in addition to the standard specification.

**2. Normative references**

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ATP: Carry perishable foodstuffs abroad in road vehicles. (Or if ATP facilities are not available: PPECB Refrigerated Road Motor Transport (24 July2014 or later)).

<sup>1</sup> WHO PQS E002 Performance specifications 31July2017.doc

Montreal Protocol- most recent standard on use of refrigerant gases.  
EN 10152: Electrolytic zinc coated cold rolled steel flat products for cold forming. Technical delivery conditions.  
EN 10169-1: Continuously organic coated (coil coated) steel flat products – Technical delivery conditions.  
ISO 9001: Quality Management Systems – Requirements.  
ISO 14001: Environmental management systems - Requirements with guidance for use.  
ISO 20282-1: Ease of operation of everyday products - Part 1: Context of use and user characteristics.  
EN 12830: 1999 (under revision), or equivalent: 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.  
WHO/PQS/E006/TR03.1: Programmable electronic temperature and event logger systems with integral alarm and auto-dialler options.  
WHO/PQS/E006/TR03-VP2.1: Programmable electronic temperature and event logger systems with integral alarm and auto-dialler options – Quality Assurance protocol.  
WHO/PQS/E006/TR05.1: User-programmable temperature data loggers.  
Directive 2002/96/EC of the European Parliament and of the Council Directive 2004/108/EC of the European Parliament and of the Council.

### 3. Terms and definitions

**Annual review:** The 12-monthly review which all PQS pre-qualified manufacturers and suppliers are required to pass in order to remain on the register of pre-qualified companies.

**Cold climate freeze prevention:** Any mechanism which prevents the temperature inside a refrigerated vehicle from dropping below +2°C, under low ambient temperature conditions, down to the temperature specified by the employer, at the time of procurement, subject to a minimum of -10°C.

**Employer:** The organisation that contracts with the Legal Manufacturer or Reseller who will supply the vehicle and maintenance advisory services described in the Performance specification<sup>2</sup>.

**Evaluator:** An individual or organisation (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:** Hot zone units must operate at a steady +43°C ambient temperature and over a +43°C/+25°C day/night cycling temperature range.

**In writing:** means communication by letter, fax or email.

**Legal Manufacturer or supplier:** 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.

**Maintenance Contractor:** A person or organisation contracted by the employer to maintain the installation.

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<sup>2</sup> *ibid.*

**Moderate zone:** Moderate zone units 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.

**QA Assessor:** the person or organisation appointed by the employer to assess the suitability of candidate approved installers, to evaluate their proposals and to monitor the installation and commissioning of the installation on site.

**QA:** Quality Assurance.

**Region:** A contiguous geographical area within which the legal manufacturer or supplier has previously supplied vehicles in low and middle income countries.

**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 units must operate at a steady +32°C ambient temperature and over a +32°C/+15°C day/night cycling temperature range.

**User:** The person responsible for the day-to-day operation and temperature monitoring of the vehicle.

#### 4. Applicability

Type-examination will be carried out by an independent **evaluator**, appointed by WHO. The examination will take place at the manufacturing site or at another agreed location. The extent of the geographical limits of any grant of pre-qualification status will be reviewed and decided upon by WHO.

#### 5. Sample-examination checklist

##### 5.1 Type-examination procedure for the evaluator

- **Step 1:** Check all demonstration samples for similarities between different models, dissimilarities between samples of one model, and any defects or damage.
- **Step 2:** Record any differences between the samples requested and those shown or received.
- **Step 3:** Complete the compliance checklist in Annex 1. Record general comments and recommendations for each section.
- **Step 4:** Take a three quarter view photograph of each of the demonstration samples.
- **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 all major specification requirements, subject to acceptable restrictions on temperature zones and **region(s)**.

## 5.2 Evidence of conformity assessment

Key components must carry the CE mark and/or equivalent internationally accepted evidence of conformity assessment.

## 5.3 Samples and supporting material

The [Legal Manufacturer](#) or [supplier](#) must supply the [evaluator](#) with a full duplicate set of the Product Dossier already supplied to WHO in accordance with the requirements of specification clause.

Demonstration samples are to be made available for inspection, as follows:

- Vehicles, bodies and refrigeration unit samples showing insulation, finishes, joint construction and 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<sup>3</sup> which the [evaluator](#) can understand; and
- JPEG image of a typical installation for inclusion in the PQS data sheet.

## 5.4 Criteria for qualification:

A final report must be issued after the type-examination 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** - Completed Annex 1 checklist; and
- **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 relevant CE certification and 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 reporting must be carried out in accordance with the requirements of this document.

### 6.2 Quality control checklist

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.

## 7. **Pre-qualification evaluation**

An applicant company will qualify for inclusion on the register of PQS pre-qualified refrigerated vehicle suppliers in accordance with WHO procedures provided the final report indicates that the components supplied by the company are likely to be able to achieve full

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<sup>3</sup> Arabic, English, French, Mandarin or Spanish.

conformity with the requirements of the Performance specification Quality assurance protocol in the [region\(s\)](#) for which pre-qualification is sought. For example, it will be acceptable if a company proposes to supply [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 pre-qualification listing.

## **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 procedures described in this document.

## Annex 1 – Compliance checklist<sup>4</sup>

This checklist must be completed by the person appointed to carry out the pre-qualification assessment.

Numeration of the following sections 4.0 to 7.0 corresponds to the *WHO PQS E002 Performance specifications 31July2017.doc*

<b>1.0 General Information</b>				
1.1	Dossier received	Yes	No	Part payment
	Examination fee received	Yes	No	Part payment
	Legal manufacturer/supplier Name			
	Address			
	Address			
	Tel			
	email			
	Fax			
	Web			
1.2	Reseller details	Applicable		Not applicable
	Name			
	Address			
	Address			
	Address			
	Tel			
	email			
	Fax			
	Web			
1.3	No. LMIC supplied.	(List):		
1.4	Supporting evidence			
1.5	Evidence OK		Yes	No

<b>4.0 Vehicle Specifications</b>				
4.1	Base Vehicle	Make and models supplied	(List):	
4.2	Drive		2X3	4X4
				6X4
4.3	Steering wheel		Left	Right

<sup>4</sup> This is a Word 'Form' document. It needs to be copied and 'protected' before it can be used for data entry. Then activate View/Toolbars/Forms and click the 'lock' icon on the Forms toolbar. See also Word Help.

4.4	Transmission	Manual	Automatic	
4.5	Fuel	Diesel	Petrol	
4.6	Colour		White	
4.7	Air conditioning	Yes		
4.8	Front towing hook	Yes		
4.9	Audible + visible reversing signals	Yes	Yes	
4.10	Lockable spare wheel,	Yes		
4.11	Lockable doors to body (with top and bottom latches), glove box, and fuel cap	Yes		
4.12	Seat belts, front side airbags	Yes	Yes	Yes
4.13	Temperature readout visible to the driver with alarm	Yes	Yes	
4.14	Temperature readouts recorded	Yes		
4.15	Programmable auto and manual control of temperature and Auto-defrost inside the body.	Yes		
4.16	Cloud-based GPS vehicle tracking			
4.17	Cloud-based internal body temperature tracking	Yes	Yes	
4.18	Lockable range of tools and jack, and instruction manual	Yes	Yes	
4.19	Models with tail lift option	(List):		
4.20	Rolling cages, pallets, fording boxes available	Yes	Yes	Yes
4.21	Vehicle speed limiter	Yes		
4.22	Transverse moveable partition	Yes		
4.23	Additional side door option available	Yes		
4.24	Fire extinguisher in the cab	Yes		
4.25	Rear cab section for overnight and rest stops	Yes		
4.26	Workshop manual, vehicle spare parts	Yes	Yes	

<b>5.0 Refrigerated body specifications</b>				
5.1	Body structure rigid. Load tie-down eyes, hooks or rails fitted	Yes	Yes	Yes
5.2	Walls, roof panels (internal and external) sub-frames, main-frames anti-corrosive treated.	Yes	Yes	Yes
5.3	Body colour white or more reflective surface finish	Yes		
5.4	Casing or the compressor body has a permanent label identifying the refrigerant in letters >10 mm high.	Yes		
5.5	Insulation foam CFC and HCFC free & compliant Montreal Protocol	Yes		

5.6	All components, excluding batteries, must not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).	Yes	
5.7	Rear two-door full opening with min. three hinges per door. Robust hinges and closing mechanism	Yes	Yes
5.8	Emergency exit available from the inside body	Yes	
5.9	Latch for doors when open 270 degrees against side of vehicle	Yes	
5.10	Cold strip curtain fitted behind the doors.	Yes	
5.11	Body insulated to 0.4W/m <sup>2</sup> /°C, or better.	Yes	
5.12	One U bend or rubber fishtail drain in each corner	Yes	
5.13	Interior lighting	Yes	
5.14	Reinforced non-slip level flooring with no obstructions	Yes	
5.15	Total body volume for each type supplied	Note:	

<b>6.0</b>	<b>Refrigeration unit</b>		
6.1	Coefficient of Performance (COP) for the refrigeration units used		
6.2	For 30°C ambient, internal temperature of 4°C heat extraction 2.25 times the heat through insulation	Yes	
6.3	-10°C ambient heating capacity available to maintained 4°C load	Yes	
6.4	Refrigerant CFC and HCFC-free & Montreal Protocol compliant	Yes	Yes
6.5	Single phase 220V-240V motor compressor, or motor-driven, Refrigeration unit able to maintain 2°C to 8°C (±2°C) at 43°C ambient temperatures	Yes	
6.6	Separate fuel tank for refrigeration from engine with provision to pump fuel from the engine tank. Cooling capacity of fuel >24 hours on full (85% of body column)	Yes	Yes
6.7	Minimum two sensors, one below the cooling unit, the other close to coldest part of anticipated load	Yes	
6.8	220V – 240V electric standby for refrigeration with automatic switch	Yes	
6.9	3-core, 15 amp extension cable >20 metres for mains back-up.	Yes	
6.10	Certification with the latest edition of UNECE Regulations	Yes	

<b>7.0</b>	<b>Warranty</b>		
7.1	Minimum three-years or 100,000 kms warranty, whichever is the shorter	Yes	

<b>Revision history</b>			
Date	Change summary	Reason for change	Approved
26 April 2017	Multiple	Consistency	
31 July 2017	Minor alterations	For consistency	
1 September	Minor edits	For consistency	