PQS type examination

WHO/PQS/E001/SDD CR-FR VP.1
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TITLE: Solar direct drive cold rooms and freezer rooms

Product verification protocol:	E001/SDD CR-FR VP.1
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Contents:

1. Scope

WHO/PQS/E001/SDD CR-FR 01-VP.1 is a verification protocol which will be used for the pre-qualification and evaluation of solar direct drive (SDD) cold rooms, freezer rooms and/or combined cold and freezer rooms (collectively CR-FR). This protocol should be read in conjunction with equipment specification **WHO/PQS/E001/SDD CR-FR 0.1** to which it refers and describes the WHO PQS specification requirements for an SDD cold room or freezer room installation, suitable for storing vaccine. Both the specification and the VP should also be read in

conjunction with **WHO/PQS/E001/PVAC** Solar power system for cold and freezer rooms (use for solar arrays when array voltage exceeds 48 V dc and/or a DC to AC inverter is included) and **WHO/PQS/E001/PV** Solar power system for vaccine refrigerator or combined vaccine refrigerator and water-pack freezer (use for solar arrays when voltage is 48 V dc or lower).

WHO/PQS/E001/SDD CR-FR0.1 also specifies the installation and maintenance advisory services that all legal manufacturers must offer in order to become pre-qualified. It applies to single storey CR-FR rooms with a gross internal cubic capacity of a minimum 5 m³ and not exceeding 40 m³. These may be housed within an existing building or as a standalone, free-standing, fully weather-proof cold room and/or freezer room not requiring additional enclosure, building or structure.

A WHO PQS Quality Assurance protocol, **WHO/PQS/E001/CR-FR01-VP.2** (Cold rooms and Freezer rooms – guidance section) completes the package. This document is initially used by an employer or their QA assessor to describe the requirements for a specific installation. The document also sets out a required proposal format and solar power system sizing options, commissioning, inspection, temperature mapping and handover procedure.

WHO/PQS/E001/SDD CR-FR01-VP.1 and a completed **WHO/PQS/E001/SDD CR-FR VP.2**, together with an employer's other documents, are intended to form the basis for a contractual agreement between the employer and the legal manufacturer or reseller for the supply of the components required for a specific installation. These documents also form the basis for a separate contractual agreement between the employer and the installer.

Three temperature zone designations are described and prequalification can be earned for any or all zones defined as hot zone, moderate zone and temperate zone.

Verification testing in accordance with this protocol will utilize a minimum solar radiation reference period (clause 5.4.2.1) below which the cold room / freezer room should *not* be installed and this VP will also establish the minimum autonomy that the cold room / freezer room can achieve. In addition, cold room / freezer rooms are tested to establish a minimum rated ambient temperature designation.

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.

BS 476-10: *Fire tests on building materials and structures. Guide to the principles, selection, role and application of fire testing and their outputs.*
Directive 2002/96/EC of the European Parliament and of the Council: *Waste Electrical and Electronic Equipment Directive.*
Directive 2014/30/EU of the European Parliament and of the Council: *Harmonisation of the laws of the Member States relating to electromagnetic compatibility*.
EMAS: *European Union Eco-Management and Audit Scheme.*
EN 10152: *Electrolytically 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.*
EN 13501-1: *Fire classification of construction products and building elements- Part 1: Classification using data from reaction to fire tests*
EN 15512: *Steel static storage systems - Adjustable pallet racking systems - Principles for structural design.*
EN 15620: *Steel static storage systems - Adjustable pallet racking - Tolerances, deformations and clearances.*
Generic Guide for the Field Evaluation of New Technologies for WHO PQS Pre-qualification.
IEC 60038: *IEC standard voltages.*
IEC 60335-1: *Safety of household and similar electrical appliances, Part 1: General requirements.*
IEC 60364-1: *Low-voltage electrical installations – Part 1: Fundamental principles, assessment of general characteristics, definitions.*
IEC 60364-4-41: *Electrical installations of buildings – Part 4*: *Protection for safety – Chapter 41: Protection against electric shock.*
IEC 60364-5-54: *Electrical installations of buildings – Part 5*: *Selection and erection of electrical equipment – Chapter 54: Earthing arrangements and protective conductors.*
IEC 62552-1: 2015 *Household refrigerating appliances – Characteristics/tests*.
IEEE 142-2007: *IEEE Recommended Practice for Grounding of Industrial and Commercial Power Systems.*
IEEE 1562: *IEEE Guide for Array and Battery Sizing in Stand-Alone Photovoltaic (PV) Systems.*
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.*
WHO/PQS/E001/CR-FR01.4: *Cold rooms and freezer rooms.*
WHO/PQS/E001/PVAC01*: Solar power systems for cold and freezer rooms.*
WHO/PQS/E001/SDD CR-FR01-VP.1: *Solar direct drive cold rooms and freezer rooms – Type- examination protocol.*
WHO/PQS/E001/SDD CR-FR01-VP.2: *Solar direct drive cold rooms and freezer rooms – Quality Assurance protocol.*
WHO/PQS/E003/PV01.4: *Solar power system for vaccine refrigerator or combined vaccine refrigerator and water-pack freezer.*
WHO/PQS/E003/PCMC 01: *Phase change material containers.*
WHO/PQS/E003/PCMC0-VP.1: *Phase change material containers- Type examination protocol.*
WHO/PQS/E006/TH02.2: *Fixed gas or vapour pressure dial thermometer.*
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.*
WHO/PQS/E007/EHC01.1: *Solar direct drive surplus energy harvest control.*
WHO/PQS/E007/EHC01 VP.1: *Solar direct drive surplus energy harvest. Control – Type examination protocol.*

3. Terms and definitions

Acceptable temperature range (freezer rooms): The acceptable temperature range for all parts of the room designated for vaccine storage must remain between -25°C to -15°C when measured under any loading condition between empty and full and over the full ambient temperature range of the required temperature zone (see clause 4.2.2).
Acceptable temperature range (cold rooms): The acceptable temperature range for all parts of the room designated for vaccine storage must remain between +2°C to +8°C when measured under any loading condition between empty and full and over the full ambient temperature range of the required temperature zone (see clause 4.2.2). Rooms specified to have cold climate freeze prevention must maintain the room temperature between +2°C and +8°C at ambient temperatures down to -10°C.
Annual review: The 12-monthly review which all PQS pre-qualified manufacturers are required to pass in order to remain on the register of pre-qualified companies.
Autonomy: Time in days that a solar power system can maintain the vaccine load within the acceptable temperature range under low solar radiation conditions (e.g., rain). Autonomy is determined as described in specification clause 4.2.4.
Back-up power: A secondary, auxiliary power source (e.g., generator) capable of independently powering 100% of all CR-FR electrical needs.
Cold climate freeze prevention: Any mechanism which prevents the temperature inside a cold room 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 ambient of -10°C.
Cool down: The time required to initially cool a walk in cold or freezer room to achieve stable operating conditions within the acceptable temperature range for vaccine storage and achieve its' full autonomy time.
Employer: The organization that contracts with the legal manufacturer or reseller who will supply the system components and the installation and maintenance advisory services described in this specification. The Employer will typically contract with an installer who will install and commission the installation under the supervision of a QA assessor and also with a maintenance contractor who will maintain the installation.
Energy harvest control (EHC): Accessory control device and/or system to enable the use of surplus solar photovoltaic electricity for powering other electricity consuming devices (loads) in addition to an immunization CR-FR. An EHC may harvest surplus electricity when the active cooling system is off and/or when the active cooling system is on and sufficient surplus electricity is available.
Freezing temperature (on walls/lining of vaccine compartment): For sensors placed in direct contact with the walls/lining of the vaccine compartment, freezing temperature is defined as any of the following conditions:
• Excursion between -0.5°C and 0°C for longer than one hour;
• Excursion equal to or below -0.5°C for any amount of time; and/or
• Inability to return to safe operating temperature (i.e., consistently between +2°C and +8°C) within two hours following an excursion equal to or below 0°C.
Hot zone: Hot zone units must operate at a steady +43°C ambient temperature and earn a minimum rated ambient temperature of +10°C or lower.
Installation: The complete cold room or freezer room installation described in WHO/PQS/E001/SDD CR-FR01-VP1.2 and in the companion WHO/PQS/E001/SDD CR-FR0.1 PQS specification document and any other employer's requirements documentation issued for a specific installation or installations, including a complete

solar power system and back-up power system where listed in the employer's requirements.
Installer: A person or organization who has been appointed by the employer to carry out the installation of the CR-FR system.
In writing: 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.
Load: Any end-use device in an electrical circuit that can consume power when the electrical circuit is energized. Load energy consumption is expressed as watt hours per day (wh/day).
Maintenance Contractor: A person or organization contracted by the employer to maintain the installation.
Minimum rated ambient temperature: The lowest continuous ambient temperature at which the acceptable temperature range can be maintained. The warmest acceptable minimum rated ambient is +10ºC.
Moderate zone: Moderate zone units must operate at a steady +27°C ambient temperature and earn a minimum rated ambient temperature of +10°C or lower.
Montreal Protocol and Kigali Amendment (2016): Montreal Protocol on Substances that Deplete the Ozone Layer and Kigali Amendment.
QA: Quality Assurance.
QA Assessor: The person or organization appointed by the employer to assess the suitability of candidate installers, to evaluate their proposals and to monitor the assembly and commissioning of the installation on site.
Region: A contiguous geographical area within which the legal manufacturer or Reseller is able to provide the full range of services describe in this specification.
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.
Rolling load: The weight applied to a cold room or freezer room floor arising from the routine use of metal wheeled manual pallet trucks and/or powered or manually operated rubber wheeled pallet lifting equipment.
Solar direct drive (SDD): solar photovoltaic power system connected to electrical load(s), without the need for a battery to sustain the acceptable vaccine storage temperature range.
Stability: The cold room / freezer room is said to be stable when:
- The internal temperatures in the vaccine storage compartment are within the acceptable temperature range; and
- The cooling system has exhibited consistent on/off operation for the final two days of this test (e.g. the same number of on/off cycles per day; and
- The temperature at each of corresponding points during successive operating cycles varies by less than ±1ºC and there is no marked trend away from the mean temperature at that point over 24 hours.

Temperate zone: Temperate zone units must operate at a steady +32°C ambient temperature and earn a minimum rated ambient temperature of +10°C or lower.
User: The person responsible for the day-to-day operation and temperature monitoring of the room.

4. Applicability

Type-examination and testing to be carried out by a WHO PQS accredited laboratory, or by a self assessment by prior agreement in writing with WHO PQS so that the assessment can be witnessed. The extent of the geographical limits of any pre-qualification status should be agreed with the WHO.

5. Specification evaluation

5.1 Evidence of conformity assessment:

Key components, such as compressors, voltage regulators, thermostatic controls and solar modules shall carry a CE or UL mark or equivalent internationally accepted evidence of conformity assessment.

5.2 Samples and supporting material:

The Legal Manufacturer or Reseller must supply WHO PQS with a product dossier in accordance with the requirements of specification **WHO/PQS/E001/SDD CR-FR0.1** Clause 7. In addition, the following specifications are to be made available:

- Paired wall panel samples showing insulation, finishes, joint construction, and panel locking arrangement(s);
- Paired roof panel samples showing insulation, finishes, joint construction and panel locking arrangement(s) (if different from wall panels);
- Paired floor panel samples showing insulation, finishes, joint construction and panel locking arrangement(s);
- Shelf and support system(s);
- If other panel types are offered, show or supply samples which cover:
  - Alternative panel thicknesses;
  - Alternative jointing arrangements;
  - Alternative surface finishes, including alternative floor finishes;
  - Construction options for different floor loading conditions;
- Examples and full technical specifications of the refrigeration units offered, including both mono-bloc and split systems as applicable;
- Thermal energy storage, including PCM components and systems;
- Examples and full technical specifications of the solar power supply system components offered;
- Examples and full technical specifications of the energy harvest control and system, if offered;
- Examples of the instruction documents described in specification clauses 4.11.1, 4.11.2 and 4.11.3 in English and a UN language which the evaluator can understand.
- Digital image of a typical installation for inclusion in the PQS data sheet.

5.3 Type-examination procedure:

Note: The type examination must take place at a location where full scale components can be inspected.

Step 1: Check all test sample(s) for any defects or damage.
Step 2: Check that the sample meets the requirements for all parts of the PQS Performance specification – Solar direct drive cold rooms and freezer rooms **WHO/PQS/E001/SDD CR-FR0.1.** Section 4. For each sub-section record detailed comments, compliance, non-compliance, supporting documentation and recommendations. Where a measured specification is required, the measured value must be stated (e.g., cool-down time in hours and autonomy in hours), "comply" or "pass" or "fail" alone is not acceptable.
Step 3: Take detailed photographs of the cold room / freezer room: all walls and ceiling of the exterior, all walls, ceiling and floor of the interior. Also take detailed photos of the cooling / heating units, all thermal storage components, temperature control system(s) and energy harvest control system (if supplied).
Step 4: Obtain any additional supporting information required in writing from the legal manufacturer or reseller and attach this information to the report.
Step 5: For each model submitted for examination tabulate the following information required for determining compliance with specifications in **WHO/PQS/E001/SDD CR-FR0.1**. 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.
• Type (i.e., cold room, freezer room or combined cold and freezer room).

The laboratory to assess whether component parts and services offered by the legal manufacturer or reseller conform to the minimum requirements set out in **WHO/PQS/E001/SDD CR-FR0.1.** For each of the following specification clauses report as instructed below and note conforms / does not conform.

4.2.2 Temperature zones: state the temperature zone. State whether the cold room has 'cold climate freeze prevention'. State the minimum rated ambient temperature. Is the appropriate temperature zone rating sticker attached to the product (see Annex 1)?
4.2.3 Temperature control: Do the laboratory test results demonstrate compliance to specification Clause 4.2.3?
4.2.4 Autonomy: Cold room and freezer room autonomy at least 120 hours as measured in Test 2 of **WHO/PQS/E001/CR-FR VP.1**.
4.2.5 Electrical safety and safety rating: Supporting documentation shows compliance of electrical and electro-mechanical components with IEC 60335-1 and this evidence is provided with the laboratory report.
4.2.6 Voltage, frequency and phasing: State all voltage and frequency offered.
4.2.7 Voltage stabilization and surge protection: Describe the equipment to protect against high or low voltage, against cycle fluctuations and against lightning-induced power surges. A circuit diagram should be included with the laboratory report.
4.2.8 Grounding: Provide details of how the grounding meets the requirements of **IEC 60364-4-41** or **IEC 60364-5-54**.
4.2.9 Foundation requirements: Provide details of how the structure *can* comply with Specification Clause 4.2.9 including seismic loading (in areas prone to earthquakes), wind loading including wind loading on the solar array (a minimum wind speed of 145 km/h), options of different types of foundation as per the shelter manufacturer's specifications and site-specific soil conditions.

4.2.10 Panel insulation: State the U values of the roof, wall and floor panels, including joints.
4.2.11 Construction: Provide details of prefabricated panel construction in accordance with Specification Clause 4.2.11 stating materials and how they meet corrosion-resistant requirements flame retardant requirements. Provide details of panel joints and how they minimize cold-bridging and air-tightness.
4.2.12 Floors: Provide details of how the floor construction complies with Specification Clause 4.2.12 including how it is applicable to store Type A or Type B or Type C including whether powered pallet lifters or pallet trucks can be used,
4.2.13 Shared walls in multi-room installations: Provide details of how the store is designed to ensure there is no risk of vaccine cartons in physical contact with the cold room side of the wall will be exposed to temperatures colder than +2°C, or that vaccine cartons in physical contact with the wall on the freezer room side will not be exposed to temperatures warmer than -15°C.
4.2.14 Door construction: Provide details of how the door construction meets the requirements of Specification Clause 4.2.14 including 100% fail-safe provision for inside opening, pedestrian access, door left-open alarm, examination window, suitability for mechanical handling equipment, heavy duty internal clear plastic strip curtain, emergency escape door (larger rooms only), internal alarm buttons.
4.2.15 Condensate management and defrost: provide details how the design meets the requirements of Specification Clause 4.2.15 including preventing exposure to high levels of humidity, provision of condensate and defrost drainage, accessibility of defrost switch(es) without accidental operation, door frame heating system.
4.2.16 Pressure relief valve (freezer rooms only): Provide details of the pressure relief valve.
4.2.17 Heater mat (freezer rooms only): Provide details of any thermostatically controlled heater mat and how this complies with Specification Clause 4.2.17.
4.2.18 Shelving: Provide details of the shelving including whether this is wall-mounted or free-standing, material of construction, the adjustability and washability.
4.2.19 Pallet racking: Provide details of the adjustable corrosion-protected pallet racking including compliance with **EN 15512** and **EN 15620**.
4.2.20 Refrigeration units: provide details of how the refrigeration units meet the requirements of Specification Clause 4.2.20 including condenser and evaporator units, provision for 100% stand-by capacity, type of refrigerant, automatic duty sharing system, timer operated electric defrosting system, condensate drip tray and drain connection, and how airtight seals are maintained within the construction.
4.2.21 Evaporator plume guard (cold rooms only): Provide details how the evaporator units are designed so that air at colder than +2°C does not reach areas where vaccine is stored. This might include details of a removable mesh cage or deflector shield around the evaporator to maintain the safe storage zone.
4.2.22 Cold climate freeze prevention (cold rooms only): Provide details of any cold climate freeze prevention protection system design to ensure cold room does not drop colder than +2°C under low ambient temperature conditions in accordance with Specification Clause 4.2.22,
4.2.23 Lighting: Provide details of internal lighting and how it complies with Specification Clause 4.2.23.
4.2.24 Alarm system: Provide details of the alarm system in accordance with Specification Clause 4.2.24 and how it complies with PQS specification **WHO/PQS/E006/AL01** or with **WHO/PQS/E006/TR03.**

4.2.25 Temperature monitoring system: Provide details of how the programmable electronic temperature and event logger system (complying with **WHO/PQS/E006/TR03)** complies with Specification Clause 4.2.25 including linkage to the alarm system specified in Specification Clause 4.2.21. Also provide details of the backup gas or vapour pressure dial thermometer complying with PQS E006/TH02).
4.2.26 Animal deterrent: Provide details of how the building design prevents entry of animals and insects into the structure and solar power system and helps discourage nesting of birds and small animals.
4.2.27 Consumables: Provide details of how consumables sufficient for two years of normal operation will be supplied.
4.2.28 Spare parts: Provide details of how spare parts sufficient for 10 years will be available at the specified location(s) including fuses/circuit breakers, thermostat control components lighting, fans, and solar power system components.
4.3.1 Ambient temperature range during transport and storage: State temperature range.
4.3.2 Ambient humidity range during transport and storage: State humidity range,
4.4.1 Room capacity: State room internal volume.
4.4.2 Overall dimensions: State dimensions of the larger components (i.e., CR-FR interior and exterior dimensions, solar array and any detached components such as back up generator system).
4.4.3 Weight: State weight and conformity with Specification Clause 4.4.3 including how lifting equipment will be supplied if necessary.
4.5.1 Solar power system: Provide details of how the solar power system complies with Specification Clause 4.5.1.
4.5.2 Back-up power system: Provide details of the required back-up power system connection. If the optional backup power supply is included provide details of how it complies with Specification Clause 4.5.2.
4.5.3 Energy harvest control and battery system (optional): Provide details of any energy harvest control system and state all loads to be powered by battery.
4.6.1 Generally: State how the design complies with Specification Clause 4.6.1.
4.7.1 Refrigerant: State the refrigerant and GWP with zero ozone-depletion potential.
4.7.2 Thermal insulation foaming agents: State the blowing agent and GWP of the foaming agent.
4.7.3 Other restricted materials: Manufacturer to declare compliance with Specification Clause 4.7.3. This declaration to be included in the laboratory report.
4.8 Warranty: Manufacturer to declare full warranty terms in accordance with Specification Clause 4.8. This declaration to be included in the laboratory report.
4.9 Servicing provision: Manufacturer to declare a design and service life of not less than 20 years. This declaration to be included in the laboratory report.
4.10 Disposal and recycling: Provide a copy of the disposal instructions from the manufacturer (in accordance with Specification Clause 4.10).
4.11 Instructions: Provide a copy of the instructions from the manufacturer (in accordance with Specification Clause 4.11).
4.11.1 Installation instructions: Provide a copy of the installation instructions from the manufacturer (in accordance with Specification Clause 4.11.1).
4.11.2 Service instructions: Provide a copy of the service instructions from the manufacturer (in accordance with Specification Clause 4.11.2).

4.11.3 User instructions: Provide a copy of the service instructions in a comprehensive, illustrated maintenance manual suitable for the user and covering all aspects of safe operation and routine non-specialist maintenance of the cold room (in accordance with Specification Clause 4.11.3). This includes health and safety procedures, compatible types of voltage stabilizer or equivalent protection systems, basic operation, cool-down time and temperature adjustment, vaccine storage instructions, maintenance tasks, defrosting, preventative maintenance checks, diagnostic (trouble shooting) and repair procedures, safe handling procedures in case of PCM leakage; itemized list of spare parts including part numbers and end-of-life resource recovery and recycling procedures.

4.12 Training: Provide details of all training options.

Acceptance criteria: Inspection indicates full conformity with all specification requirements, subject to acceptable restrictions on temperature zones[1] and region(s). Evidence must be provided where required.

Rejection criteria: Failure to meet any of the specification requirements.

5.4 Performance test procedure

5.4.1 Acceptance criteria

The test results shall demonstrate the following acceptance criteria:

The temperature distribution within the designated vaccine storage area of the temperature-controlled room is maintained within the range specified for the products being stored (e.g. +2°C to +8°C for cold rooms and -25°C to -15°C for freezer rooms). The qualification procedure shall be able to assess actual product temperatures for commonly used internal load layouts. Pre-qualification testing shall be carried out at the ambient temperature extremes anticipated within the proposed climate zone.

The above acceptance criteria shall be demonstrated using the test clause 5.5.1, clause 5.5.2 clause 5.5.3 and clause 5.5.4 if the optional energy harvest is included.

5.4.2 General test conditions

Temperature sensor data shall be recorded every minute in accordance with **IEC 62552** Clause A.2.6. Temperature reading uncertainty[2] no greater than ±0.5°C.

[1] For example, it will 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 shall be excluded from the pre-qualification listing.

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

5.4.2.1 Simulated solar power supply

Power supply to be set up based on manufacturer's specification. For testing purposes, a means of simulating the solar day shall be arranged to take into account the varying amount of solar radiation from dawn to midday to dusk with a 12 hour night. Note that the solar array maximum open circuit voltage is limited to 600 volts dc.

3.5 kWh/m²/day
1 hour at 50 W/m²
2.5 hours at 250 W/m²
0.5 hours at 350 W/m²
4 hours at 450 W/m²
0.5 hours at 350 W/m²
2.5 hours at 250 W/m²
1 hour at 50 W/m²

5.4.2.2 Ambient temperature

All SDD CR-FR will be first tested at Hot zone temperatures. Legal manufacturers may offer products suitable for one or more temperature zones (i.e., Hot zone, Temperate zone and/or Moderate zone) and may restrict their offerings to one or more named regions. Optionally, SDD CR-FR may be tested at Temperate zone and/or Moderate zone in order to establish performance data for those climates and earn prequalification limited to those climate zones.

If a finely controlled environment test room is not available or is too small to house the cold room / freezer room, the unit under test should be housed in a warehouse or other large building where the ambient temperature can be controlled and humidity does not change significantly for the duration of the test. Mean ambient temperature to 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 shall be at least 6 external sensors free from influence of generated heat (e.g., not in direct sunlight and away from any heat generators or from air blowing from the refrigerated unit). These shall be centred 10 cm from the external surface of the cold storage wall. For large external surfaces, there shall be at least 2 external temperature sensors.

5.4.2.3 Internal temperature measurements:

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 include the corners, places near door(s), and weak locations where heat ingress may be expected, (e.g., near a door or an externally

sited compressor). Taking into account the size of the cold storage area, there shall be at least 18 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[3]).

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

5.4.2.4 Internal loading

Testing shall take place with the cold room / freezer room substantially empty, apart from shelving or pallet racking units, where fitted. An empty load with a number of brass-barrel temperature sensors will simulate a worst-case scenario where the small thermal mass (the brass barrels) may be subject to over-cooling or under-cooling in various ambient air temperatures.

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

5.4.2.5 Energy harvest control

If an optional energy harvest control (EHC) system is included then all tests shall be conducted with the EHC system connected and operating. If known electrical loads will be standard equipment included in the CR-FR (e.g., lights) the known loads are to also be connected and operating. Following successful completion of Tests 1, 2 and 3 described below any SDD CR-FR with and EHC shall also carry out Test 4. Legal manufacturer to clearly state all loads that are connected to a battery.

5.5.1 Test 1: Cool down, energy consumption and stability test

Power: Set the simulated solar power as clause 5.4.2.1.
Step 1: Set the test chamber temperature to +43°C (hot zone) and/or alternate chamber temperatures +32 (temperate zone) and/or +27C (moderate zone) with the CR-FR empty, the door(s) open and the power supply switched off until stable temperatures can be shown for at least 48 hours. Any internal or external thermal energy storage component (e.g., PCM) must be preconditioned at the same CR-FR temperatures.
Step 2: Close the door(s) of the CR-FR, switch it on and allow it to reach working temperature and stabilize.
Step 3: During pre-stabilization, cool down and stabilization, record temperatures every minute until test is complete. Measure energy consumption in kWh/day for cool down time and for the stability stages of this test. Determine the compressor or cooling system duty cycle.

[3] Note: Vaccine load limits must be clearly indicated inside the storage area facilitate for correct loading.

Step 4: Chart all temperatures during the cool down and stability stages. Show cooling system cycling on the same chart if possible. Record maximum current (e.g., full load amps) required to start cooling equipment (kW).
Step 5: For the stability stage, report the overall mean, maximum and minimum temperatures plus the means for each internal and external temperature sensors.

Initial stabilization is accomplished when the CR-FR demonstrates the following:

- Internal temperatures are stabilized within the acceptable temperature range;
- Cooling system is stabilized when it exhibits consistent on/off operation for two consecutive days of this test (e.g. the same number of on/off cycles per day): and
- The test time period equals or exceeds the cool down time specified by the legal manufacturer, plus one day

Step 6: Report the times in hours for the different stabilities as above. Report kWh/day consumption for both cool down and stability (i.e., consistent cooling system on/off operation for two consecutive days). Report maximum current (e.g., full load amps) required to start cooling equipment (kW).

Note that full stabilization is achieved when the CR-FR is able to meet all performance criteria during cool down test and is at least as long as the cool time specified by the manufacturer.

Acceptance criteria: Stabilized internal temperatures maintained with the acceptable temperature range in accordance with Clause 3. Definition and Terms. For cold rooms no freezing temperatures recorded in the vaccine storage area(s) will be accepted. No standard set for the cool down time or energy consumption during stability but the cool down periods[4] and energy consumption averaged over the final two days will be reported as kWh/day at the continuous test temperature (hot, temperate or moderate zone).

Rejection criterion: Failure to stabilize within the acceptable temperature range. If the CR-FR does not initially stabilize within the period specified by the legal manufacturer, plus one day, consult with the manufacturer.

5.5.2 Test 2: Autonomy

Note: all CR-FR to be tested at hot zone temperature. Optionally, the CR-FR can be tested at moderate or temperate zone to earn a conditional prequalification at those climate zones. For example, a CR-FR can fail hot zone autonomy testing but can pass at temperate zone and earn prequalification at temperate zone only.

Power: Set the simulated solar power as clause 5.4.2.1.
Step 1: Stabilise the test chamber temperature +43°C.

[4] Note there are different cool down times, to temperature stability, to cooling system stability and to full stability where the CR-FR can exhibit all performance requirements including autonomy.

Step 2: Autonomy test to be begin immediately after 48 hours of stability in Test 1 with cold rooms in full stabilization between +2°C and +8°C or freezer rooms in full stabilization between -15 and -25C.
Step 3: Reduce the simulated solar power supply to the CR-FR at the time when the compressor or cooling system is turned off at the end of the 12-hour solar day to the same voltage and daily runtime as specified by the manufacturer, but no more than 5% of the maximum solar array current specified by the manufacturer based on the solar radiation reference period. No power can be supplied to the compressor or cooling system from a battery or back-up power supply (i.e., mains or generator).
Step 4: Record temperatures every minute. Measure electricity consumption and the cooling system duty cycle over the test duration and report energy consumption in kWh/day, the percentage on-time during the 12-hour solar phase and graphically display these on-off cycles on the same chart as the recorded temperatures.
Step 5: Discontinue testing when the warmest internal temperature sensor systematically exceeds +8°C (cold rooms) or is systematically warmer than -15°C (freezer rooms).
Step 6: Record the elapsed time in hours since beginning of the test and report as the autonomy. Record and report the position of the warmest sensor.

Acceptance criterion: Cold room and freezer room autonomy to be at least 120 hours when tested for the hot zone.

Rejection criterion: Autonomy less than 120 hours.

5.5.3 Test 3: Minimum rated ambient temperature (cold rooms only)

Power: Set the simulated solar power as clause 5.4.2.1.
Step 1: Stabilise the test chamber temperature to M:+27ºC, T:+32°C, H:+43°C.
Step 2: Switch the cooling system on and stabilize cold rooms between +2°C to +8°C. Stable temperatures must be exhibited for at least 24 hours.
Step 3: At the rate of 6 degrees per hour, decrease the test chamber temperature to +10ºC or at a lower temperature specified by the manufacturer rounded up or down to the nearest 5ºC.
Step 4: Run the test for a further 72 hours at least at the minimum rated ambient achieved in Step 3.
Step 5: Record temperatures every minute and chart temperatures for each stage: Warm ambient stability – transition – cold ambient. Also state the warmest and coldest interior and exterior temperatures for warm ambient and for the cold ambient.

Acceptance criteria: Stabilized internal temperatures maintained with the acceptable temperature range in accordance with clause 3 Terms and definitions. For cold rooms no freezing temperatures recorded in the vaccine storage area(s).

The result will be printed in the blue sector of the temperature zone symbol (see Annex 1).

Rejection criterion: Failure to stabilize within the acceptable temperature range in accordance with Clause 3, Terms and Definitions at the declared minimum rated ambient temperature. The warmest acceptable minimum rated ambient temperature is +10ºC.

5.5.4 Test 4: Energy harvest control

See **WHO/PQS/E007/EHC01/VP.1** and substitute SDD CR-FR for SDD appliance and carry out all tests.

Acceptance criteria: Performance in accordance with all **WHO/PQS/E007/EHC01/VP.1** requirements.

Rejection criterion: Failure of any **WHO/PQS/E007/EHC01/VP.1** test or requirement.

5.6 Test criteria for qualification

A final report should be issued after the **WHO/PQS/E001/SDD-CR-FR01-VP1.1** assessment is complete. The report must contain the following data and analyses:

1. Summary: Conclusions and recommendations.
2. Scope: Review of samples and construction options included in the type examination Clause 5.3, Step 5, including a list of any that is specifically excluded.
3. Photographs: All photographs as described in Clause 5.3 Step 3.
4. Temperature zone(s): Assessment of the temperature zone(s) for which the product is suitable.
5. Region(s): Assessment of the region(s) within which the product should be pre-qualified.
6. Type examination: Report whether the cold room / freezer room meets all requirements stated in PQS specification reference **WHO/PQS/E001/SDD CR-FR0.1** including reference to supporting documentation (e.g. compliance certificates or test reports). Where a measured specification is required, the measured value must be stated; “comply” or “does not comply” (note: “pass” or “fail” will not be accepted).
7. Test results from each test demonstrating the temperature distribution within the vaccine storage area of the cold room / freezer room is maintained within the acceptable temperature range as defined in clause 5.4.1 in this document.
8. A current **ISO 9001** certificate and a copy of the applicant’s current **ISO 14001** certificate.
9. Relevant CE or UL certification or other conformity assessment certificates. It is expected that key components such as compressors, voltage regulators, thermostatic controls, thermal energy storage, including PCM components, and solar power components will carry a UL mark or other internationally accepted evidence of conformity assessment.
10. Annexes: Additional supporting documentation requested and received from the legal manufacturer or supplier during the course of the type-examination.

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. 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 a specific and completely integrated assembly for inclusion on the register of PQS pre-qualified solar direct drive cold rooms and freezer room, in accordance with WHO procedures, provided the final report shows that the cold room or freezer room supplied by the company will achieve full conformity with the requirements of specification **WHO/PQS/E001/SDD CR-FR0.1** and verification protocol **WHO/PQS/E001/SDD-CR-FR01-VP0.1** in the region(s) for which pre-qualification is sought.

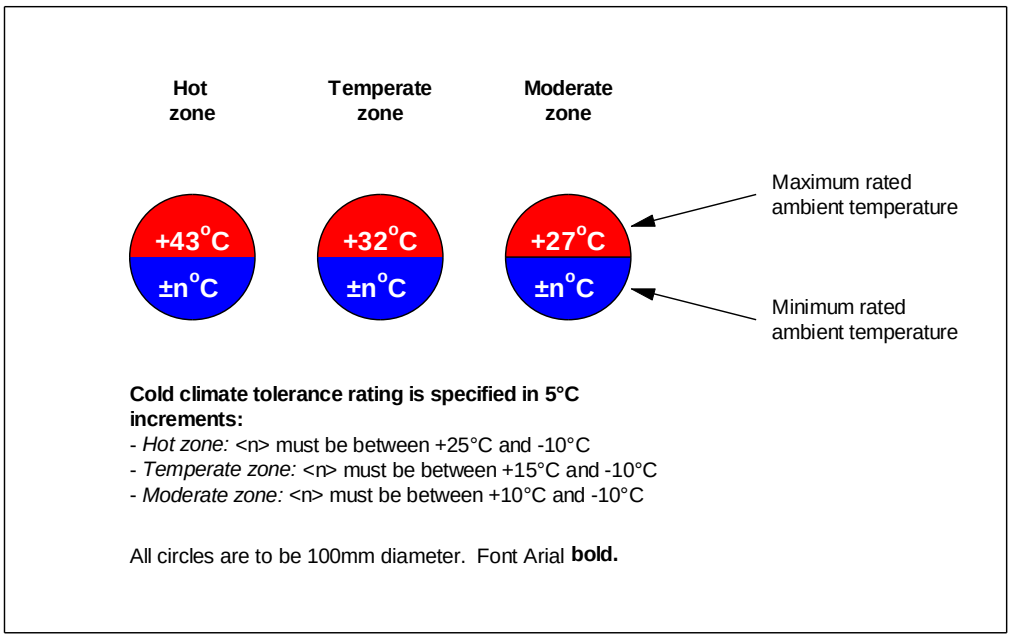
8. Modified products

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

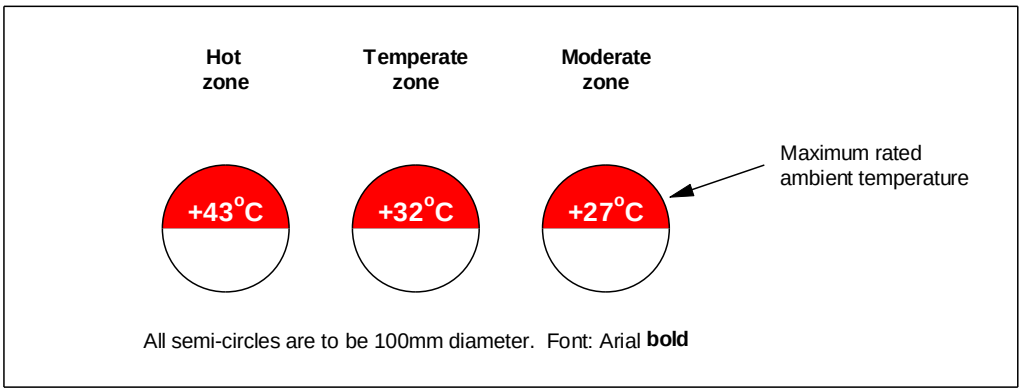
Annex 1 – Temperature zone symbols

Cold room symbols Note to PQS Secretariat – Please revise the symbols to MRA language. Suggested wording:

1.) **Delete all text from "Cold climate tolerance … +10C to -10C"**
2.) **Replace with "Minimum rated ambient for all zones to be +10°C or lower".**



Freezer room symbols



Annex 2 - Internal temperature sensor locations

The following figures show an example of where temperature sensors may be placed. Possible sensor positions are indicated by an 'X'.

Figure 1: Side elevation

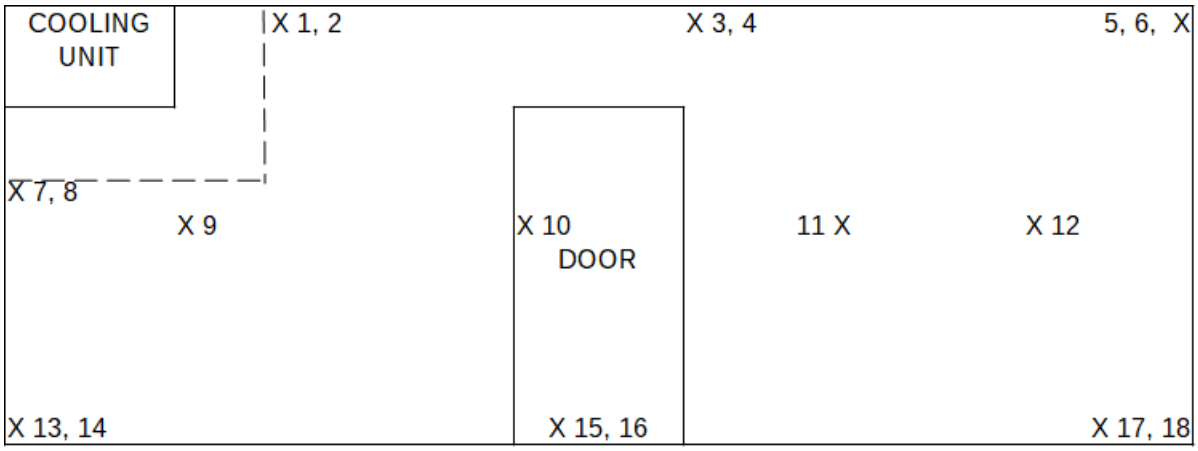
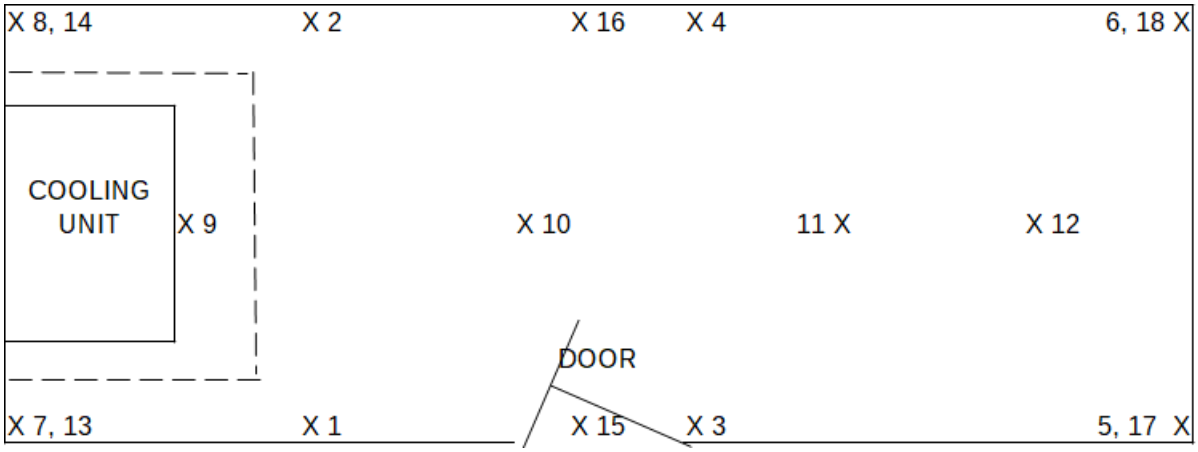


Figure 2: Plan



Notes on sensor positions

The extreme warmest and coldest places within the defined vaccine storage space must be captured including near the door(s) and near any cooling unit(s) up to the edge of the load limit if defined.

It is anticipated that vials will be stored at least in secondary or primary and secondary packaging therefore all sensors to be placed 5 cm away from the walls, ceiling and floor except where a load limit is clearly indicated in which case they should be right up to or against this load limit.

If there is no load limit then sensors to be placed 5 cm away from any cooling system unit. If there are any cooling units or elements (e.g., thermal storage, refrigerant tubing) within any wall or surface, the sensor should be placed against this surface.

If there are additional doors or cooling units, additional sensors to be placed 5 cm away from the edges of the additional door(s) or cooling unit(s) to explore any weaknesses

The test report shall show the position of the temperature sensors labelled for reference in the report.

Revision History

Date	Change summary	Reason for change	Approved