



TITLE: Solar direct drive cold rooms and freezer rooms

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1. Scope:

WHO/PQS/E001/SDD CR-FR01 describes the performance requirements for a generic cold room or freezer room (CR-FR) [installation](#) of equal or greater performance to **WHO PQS E001 CR-FR01.4** specifications, suitable for storing vaccine, assembled using prefabricated insulated panels or as a site-built structure which could be situated outside. The CR-FR must include pre-packaged cooling system(s) to be electrically powered with a [solar direct drive \(SDD\)](#) power system. It also specifies the installation and maintenance advisory services that all [legal manufacturers](#) must offer in order to become pre-qualified.

All CR-FR cooling requirements are considered to be critical electrical loads due to the large volume and value of vaccines that can be stored within.

The [autonomy](#) time for solar electric systems powering critical loads has been defined as a minimum of five days per normative reference **IEEE 1562**. The CR-FR cooling system must include a [back-up power](#) generator connection

(AC or DC generator). A [back-up power](#) supply is recommended. Battery powered cooling systems are not included in this specification however battery/inverter powered systems are included in the **WHO PQS E001/PVAC** specification.

This specification applies to single story rooms with a gross internal cubic capacity from 5 m³ to 40 m³, 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.

[Energy harvest control \(EHC\)](#) is an option and is an acceptable means for directly powering non-essential cooling [loads](#) and / or recharging battery-supported secondary loads (e.g., communications, lighting). Battery storage is not acceptable for powering the essential cooling system and CR-FR electrical resistance heating elements, if included.

The following documents are associated with this specification (use most recent versions).

- **WHO/PQS/E001/SDD CR-FR-VP.1** is a testing and type-examination protocol which will be used for pre-qualification evaluations.
- **WHO/PQS/E001/SDD CR-FR-VP.2** is completed by an [employer](#) or his [QA assessor](#) and sets out the requirements for a specific installation. The document also specifies the requirements for the [legal manufacturer](#) or [reseller](#) proposal format, [SDD](#) power system sizing, [installation](#), commissioning and handover procedure. The completed protocol should be read in conjunction with **WHO/PQS/E001/SDD CR-FR**, to which it refers.
- **WHO/PQS/E001/PVAC** or **WHO/PQS/E003/PV** will define specifications for the solar power system.
- **WHO/PQS/E007/EHC** will define the requirements for [energy harvest control](#) systems, if included.
- **WHO/PQS/E007/EHC VP.1** will define laboratory test requirements for energy harvest systems, if included.

WHO/PQS/E001/SDD CR-FR 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](#). This also forms the basis for a contractual agreement between the [employer](#) and the [approved installer](#).

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.*

IEEE 1562: *IEEE Guide for Array and Battery Sizing in Stand-Alone Photovoltaic (PV) Systems.*

IEEE 142-2007: *IEEE Recommended Practice for Grounding of Industrial and Commercial Power 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/PCMC01: *Phase change material containers.*

WHO/PQS/E003/PCMC0-VP01: *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 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.

Design day: for purposes of sizing the solar power system, the design day requires the largest of the following three options for sizing the solar array to meet all CR-FR electrical load requirements: 1) based on the lowest monthly solar radiation reference period; 2) based on the highest average daily electrical load requirement for a given month; or 3) both simultaneously.

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 circuit is off and/or when the active cooling circuit 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 $+2^{\circ}\text{C}$ and $+8^{\circ}\text{C}$) within two hours following an excursion equal to or below 0°C .

Hot zone: Hot zone units must operate at a steady $+43^{\circ}\text{C}$ ambient temperature and earn a minimum rated ambient temperature of $+10^{\circ}\text{C}$ or lower.

Installation: The complete cold room or freezer room installation described in WHO/PQS/E001/SDD CR-FR01-VP1.1 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 $+10^{\circ}\text{C}$.

Moderate zone: Moderate zone units must operate at a steady $+27^{\circ}\text{C}$ ambient temperature and earn a minimum rated ambient temperature of $+10^{\circ}\text{C}$ 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.

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. Requirements

4.1 General:

4.1.1 *Initial pre-qualification*

A **legal manufacturer** or **reseller** seeking prequalification under the terms of this specification must satisfy WHO that they are able to supply a complete package of components, including an installation and maintenance advisory service to enable a competent **installer** to install and commission the installation and to enable a competent **maintenance contractor** to maintain the system. The **SDD WICR-FR** must perform acceptably in a series of tests in a climate-controlled chamber as described **WHO/PQS/E001/SDD CR-FR VP.1**. In-house testing may be proposed to the WHO PQS Secretariat and only allowed if approved in advance **in writing**. **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**.

4.1.2 *Extended region pre-qualification*

Pre-qualified **legal manufacturers** or **resellers** who wish to extend the **region(s)** for which they are already pre-qualified may do so at the time of the **annual review** by providing WHO with supplementary evidence **in writing** that they are able to offer the complete service described in this specification to the additional **region(s)**.

4.1.3 *Field evaluation*

Prior to PQS pre-qualification a WHO PQS pre-approved field evaluation shall be required in accordance with the requirements of the **Generic Guide for the Field Evaluation of New Technologies for WHO PQS Pre-qualification**.

4.2 Performance:

4.2.1 *General requirements:*

All component parts and services offered by the **legal manufacturer** or **reseller** must satisfy the minimum requirements set out in this specification.

4.2.2 *Temperature zones and minimum rated ambient temperature:*

Provide **hot zone**, **temperate zone** or **moderate zone** equipment as required for a specific installation and climatic conditions. All zones will require that the CR-FR earn a **minimum rated ambient temperature** of +10°C or colder.

Where a cold room is required to have optional ‘cold climate freeze prevention’ it must maintain the vaccine compartment between +2°C and

+8°C at ambient temperatures down to -10°C. Where a freezer room is required to have optional ‘cold climate freeze prevention’ it must maintain the vaccine compartment between -15°C and -25°C. Legal manufacturer to declare the [minimum rated ambient temperature](#). In all cases the appropriate temperature zone rating sticker must be attached to the product before handover (see Annex 1).

4.2.3 *Temperature control:*

Room temperature must be controlled by a thermostat within the tolerances specified below. The thermostat must be calibrated to ITS-90 and be accurate to $\pm 0.5^\circ\text{C}$ or better.

- **Cold room:** 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). Any area within the designated vaccine storage area that reaches [freezing temperature](#) must be physically excluded from vaccine storage. 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.
- **Freezer room:** 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). Rooms specified to have [cold climate freeze prevention](#) must maintain the room temperature between -15 and -25°C.

4.2.4 *Autonomy*

A cold room or freezer room when combined with an [SDD](#) power system must provide a minimum of five days of [autonomy](#). The actual on-site [autonomy](#) (of greater days) can be calculated using one of the two methods defined in the normative reference: Toma, H. and Markvart T. *Solar Autonomy Calculation Tool*, University of Southampton, UK, 2009. If a calculated on-site [autonomy](#) is more than five days then the CR-FR must have an equal or greater [autonomy](#) in order to be installed at that site. In no case can the solar power system have an [autonomy](#) of less than five days. The two calculation methods are:

1. selection of [autonomy](#) for the specific locations listed in the supporting document to the *Solar Autonomy Calculation Tool*¹, or
2. calculation of [autonomy](#) using the formulas and the required long term daily solar radiation data as described in the *Solar Autonomy Calculation Tool*¹

The installation must then be sized to provide the required [autonomy](#) at the specified location. An SDD CR-FR cannot rely on a battery to power the cooling system to sustain [acceptable temperature range](#).

4.2.5 *Electrical safety and safety rating:*

Voltage of electrical system to be clearly posted with permanent signage. Any voltage equal to or greater than 120 volts (AC or DC) to be clearly labelled as

¹ Instructions for Autonomy Calculation (For Solar Vaccine Refrigeration Systems per the WHO PQS). Table 1 includes a subset of sites for which the data are considered to be sufficiently accurate for solar vaccine storage applications.

“Danger: High Voltage”. Electrical safety rating: Manufacturer to certify compliance of the supplied electrical and electro-mechanical components with **IEC 60335-1**. All on-site electrical installation work must comply with local and national codes and **IEC 60364-1**.

4.2.6 *Voltage, frequency and phasing:*

Electricity input to power the primary cooling system(s) of the installation may be direct current (DC), alternating current (AC) or a combination of DC and AC. The following options may be offered:

- **DC Input voltage** not to exceed 600 volts DC. For voltages greater than 150 VDC, the wires must not be easily accessible and must be installed in metallic conduit with the exception of immediate solar module output cables. For rooms with gross capacity from 5m³ to 40 m³.
- **AC Single-phase:** 220–240-volt 50/60 Hz and 100-127 volt 50/60 Hz single-phase neutral and earth (for rooms not exceeding 10 m³ gross capacity).
- **AC Three-phase:** 190-240 volt 50/60 Hz and 380-480 volt 50/60 Hz three-phase neutral and earth (for rooms greater than 10 m³ gross capacity). Y/delta starters are required to minimize starting current and back-up power system capacity.

4.2.7 *Voltage stabilization and surge protection:*

Unless specifically excluded in a tender invitation, provide equipment to protect against high or low voltage, against cycle fluctuations and against lightning-induced power surges. The equipment must be compatible with the electricity supply installation at the site where the store is to be constructed. See clauses 4.5.1 and 4.5.2.

4.2.8 *Grounding:*

Grounding of the building shall be as per local codes and requirements or **IEC 60364-4-41**, **IEC 60364-5-54** and **IEEE 142-2007**. The grounding impedance must be 5 ohms or less when measured from the earth grounding point(s) to the solar module frame at the farthest distance from the earthing electrode(s). Further, the resistance from the electrode system to earth must be 5 ohms or less.

4.2.9 *Foundation requirements:*

The foundation design shall consider conditions specific to the location. (e.g., piers for sites prone to flooding).

Seismic loading shall be considered in areas prone to earthquakes.

Wind loading design shall be required. The foundation shall be designed for the forces sustained by the shelter and other equipment under maximum wind speed anticipated for the site. If solar array is attached to the shelter, wind load design must be for the complete assembly. A minimum wind speed of 145 km/h shall be used.

The following foundation types are acceptable:

- Slab
- Footings
- Piers
- Screw-in pilings
- Columns
- Grade beams

The foundation shall be designed as per the shelter manufacturer’s specifications and site-specific soil conditions. An analysis of the soil shall be performed to determine whether the soil is adequate to properly support the foundation. The foundation plans shall be designed by a qualified engineer. The foundation shall be constructed as per the approved design by a qualified contractor.

Any excavations done for the foundation shall follow local rules and regulations. The site shall be graded to slope away from the foundation, provide water run-off, and prevent standing water.

4.2.10 Panel insulation:

The average thermal transmittance (U value) of the roof, wall and floor panels, including joints, must be 0.25 W/m²K or better in moderate and temperate zone applications and 0.17 W/m²K or better in hot zone applications. Foam insulation must comply with clause 4.7.2; if flammable it must contain a fire-retardant.

4.2.11 Construction:

If prefabricated panel construction, then wall and roof panel skins must be made from either:

- Stainless steel.
- Zinc coated steel sheet to **EN 10152** with a corrosion-resistant plastics coating to **EN 10169-1** and with a surface spread of flame rating meeting **EN 13501-1** category B-s3d or **BS 476**, Class O.

Prefabricated panels must be fully insulated and without internal structural members or stiffeners between the skins. Tongued and grooved joints between panels must be designed to minimize cold-bridging. Gaskets must be resistant to damage from oil, fats, water and detergents. After assembly, all joints must be sealed on the interior side to ensure airtightness. Roof panels with an overall length of 6 metres or less must be self-supporting. Where larger span enclosures are required, additional support will be subject to site-specific design.

4.2.12 Floors:

If prefabricated panel construction where floor panels are used, it must have a hard-wearing, non-slip finish and must conform to one of the loading requirements in the table below, as specified by the employer.

Store type	Static load (distributed)	Concentrated load (300 x 300 mm)	Concentrated load (25 x 25mm) ^a	Rolling load
Type A: Shelving store with pedestrian traffic only	1,500 kg/m ²	900 kg	400 kg	N/A
Type B: Shelving store with light duty trolley	1,500 kg/m ²	900 kg	400 kg	250 kg
Type C: Shelving store and/or pallet store with manual pallet truck	1,500 kg/m ²	900 kg	400 kg	400 kg

a. Concentrated loads of 400 kg over 25 x 25 mm require a concrete floor. This includes any room with pallet racking.

Where powered pallet lifters and pallet trucks are used, the floor should be constructed in-situ in accordance with the following minimum specification; final details will be subject to site-specific design:

- Reinforced concrete subfloor to suit site conditions.

- Extruded polystyrene slabs laid with the joints staggered to achieve a ‘U’ value of 0.17 W/m²K or better.
- 250 micron polythene vapour barrier.
- Reinforced granolithic concrete topping trowelled smooth.

Concrete floors must be designed and constructed to allow for level entry to the cold room or freezer room. Shallow ramped access is acceptable for panel-based floors. Minimum floor to ceiling height of 2 metres.

4.2.13 *Shared walls in multi-room installations:*

In multi room installations with shared walls, the construction of the shared wall(s) between adjoining cold rooms and freezer rooms must be designed so as to ensure that there is no risk that vaccine cartons in physical contact with the cold room side of the wall will be exposed to temperatures below +2°C, or that vaccine cartons in physical contact with the wall on the freezer room side will be exposed to temperatures above -15°C. Spacer devices may be employed to prevent such direct contact.

4.2.14 *Door construction:*

Doors must be constructed and insulated to the same standard as clauses 4.2.8 and 4.2.9. Doors must be lockable with 100% fail-safe provision for opening from inside.

- **For pedestrian access only:** The clear opening width of the door must be 800 mm minimum. The clear door opening height must be 1975 mm minimum. An internal clear plastic strip curtain shall be provided.
- **Door left-open alarm** to sound after 30 seconds. This can be de-activated for 5 minutes to allow for larger stock movement.
- **Examination Window** (view port) required.
- **For mechanical handling equipment:** Where mechanical handling equipment is used, the door width and height must be specified by the [employer](#) to suit the mechanical handling equipment and pallet formats specific to the room. Single hinged doors, double hinged doors or sliding doors are possible alternative options. Provide a heavy duty internal clear plastic strip curtain.
- **Emergency escape door:** Where required by local building or fire escape regulations, provide an emergency pedestrian escape door at the opposite end of the room from the main entrance (larger rooms only).
- **Internal alarm button** at all doors.

4.2.15 *Condensate management and defrost:*

The conditions within the designated vaccine storage locations must be designed so that vaccine primary, secondary and tertiary packaging is not exposed to levels of humidity which may cause damage to cartons or primary container labels or create a risk of mould growth. To alleviate humidity damage legal manufacturers are to include design features and/or provide containers for vaccine storage. Condensate and defrost drainage must be provided in all refrigeration and freezing compartments. If used, the defrost switch (or switches) must be accessible to the user without tools but must be protected from accidental changes in position. Provide a door frame heating system for all freezer rooms and for cold rooms in humid climates. Battery supported heating elements are not allowed.

4.2.16 Pressure relief valve (freezer rooms only):

Provide a pressure relief valve in the roof or wall of all freezer rooms.

4.2.17 Heater mat (freezer rooms only):

If required, provide a heater mat, with thermostatic control, to prevent frost heave (ground floor location) or ceiling condensation (upper floor location) below freezer room floor panels. Heating may be supplied as an integral part of the floor panel construction. Battery supported heating elements are not allowed.

4.2.18 Shelving:

Wall-mounted or free-standing stove enamelled steel, galvanized steel, stainless steel, aluminium or plastic adjustable slatted shelving units to carry vaccine in packages. Shelves must be not less than 450 mm and not more than 600 mm deep at approximately 450 mm vertical centres. The top face of the lowest shelf must be mounted 200 mm above the floor. Each shelf must be rated to support at least 0.075 kg/cm². Shelving must be washable. Shelving layouts are subject to installation-specific design but must make efficient use of available space.

4.2.19 Pallet racking:

Free standing adjustable corrosion-protected pallet racking must comply with **EN 15512** and **EN 15620**. Subject to the requirements of local building standards and regulations and site-specific engineering design, the racking system may be used to provide intermediate support for the insulated roof panels.

4.2.20 Refrigeration units:

Depending upon the internal room layout and the room location, active refrigeration units may be one of the following types:

- Wall-mounted with the condenser unit discharging inside the building that houses the cold room (monobloc system);
- Wall-mounted with outdoor condenser units located externally as close as possible to the evaporator units (weatherproof split system); or
- Wall-mounted with condenser units located in a separate ventilated enclosure mounted as close as possible to the evaporator units (split system).

Refrigeration unit installations must:

- Be sized to give 100% stand-by capacity under worst-case conditions;
- Use refrigerant complying with clause 4.7.1;
- Have an automatic duty sharing system designed to ensure even wear on the refrigeration units. All units should be fitted with run-hour meters.
- Have timer operated electric defrosting system with a condensate drip tray and drain connection.
- Have airtight seals between monobloc units and wall panel cut-outs.
- Have airtight seals around all pipe and cable penetrations through wall and/or roof panels.

4.2.21 Evaporator plume guard (cold rooms only):

Size and position the evaporator units so that the plume of discharged air at a temperature below +2°C does not reach areas where vaccine is stored. If necessary, provide a removable mesh cage or deflector shield around the evaporator so as to maintain the safe storage zone.

4.2.22 Cold climate freeze prevention (cold rooms only):

Where **cold climate freeze prevention** is specified provide a low-temperature protection system to prevent the temperature of the cold room dropping below +2°C under low ambient temperature conditions, down to an ambient of -10°C or lower temperature when specified by the **employer**, at the time of procurement.

4.2.23 Lighting:

Provide internal ceiling-mounted LED luminaires with an external switch and pilot light. One external light and light switch must be fixed to the wall of the cold room enclosure near to the entrance door. The minimum illumination level on the vertical face of the lowest shelves must be 150 lux. Lights included as a standard component may be powered by batteries recharged by the **SDD** or with an **EHC** option.

4.2.24 Alarm system:

Provide an audible and visible alarm with battery backup and automatic recharge, which is triggered in the event of power system failure or when freezer room temperatures are outside set limits. The alarm must comply with PQS specification **WHO/PQS/E006/AL01**, or with **WHO/PQS/E006/TR03** if a component part of an event logger system. Alarm sounders are to be located adjacent to the cold room/freezer room. Remotely located repeater alarm sounders and/or flasher units may be required if specifically requested by the **employer**.

It is recommended to provide an alarm system to send SMS messages to user(s) where feasible.

4.2.25 Temperature monitoring system:

As required for the specific installation, provide:

- A programmable electronic temperature and event logger system with auto-dialler complying with **WHO/PQS/E006/TR03** linked to the alarm system specified in clause 4.2.21.
- Provide a backup gas or vapour pressure dial thermometer complying with **PQS E006/TH02**, mounted on the wall of the cold room in an accessible position.

4.2.26 Animal deterrent:

The building shall be designed to prevent entry of animals and insects into the structure. The design should help discourage nesting of birds and small animals on exterior features of structure.

4.2.27 Consumables:

Provide consumables sufficient for two years of normal operation at the specified location(s).

4.2.28 Spare parts:

Provide spare parts sufficient for 10 years of normal operation at the specified location(s). At a minimum, spares shall include fuses/circuit breakers, thermostat control components (e.g., sensors, sensor cables, logic cards) lighting, fans, and solar power system components (e.g., solar module, array cable, solar direct drive control, inverter logic card).

4.3 Environmental requirements:

4.3.1 Ambient temperature range during transport and storage:

-30°C to +70°C when components are in transit.

4.3.2 *Ambient humidity range during transport, storage and use:*
5% to 95% RH, non-condensing.

4.4 Physical characteristics:

4.4.1 *Room internal volume:*

Room volume minimum of 5m³ up to 40 m³.

4.4.2 *Overall dimensions:*

Individual components must generally be able to fit through an 800 mm wide door opening (with the door leaf removed if necessary).

4.4.3 *Weight:*

Component elements of the room enclosure and component elements of the refrigeration unit(s) must be capable of being manually handled safely into their final positions. Mechanical lifting equipment will typically not be available. Panels and refrigeration units will generally be lifted into position using manual labour only. It is recommended that the CR-FR and any associated components be designed for lifting in such a way that no single worker is required to carry more than 25 kg whilst working on their own, or in a group.

- If mechanical lifting equipment is required, this will have to be provided by the [installer](#), taking full account of site access restrictions.

4.5 Interface requirements:

4.5.1 *Solar power system:*

Solar power system to comply with **WHO/PQS/ E003/PV01** specifications when nominal system voltage is less than or equal to 48 Vdc. For solar power systems when nominal system voltage is greater than 48 Vdc system to comply with **WHO/PQS/ E001/PVAC** specifications. In no cases can solar array open circuit voltage exceed 600 Volts DC.

4.5.2 *Back-up power system:*

The CR-FR cooling system must include a [back-up power](#) generator connection (AC or DC generator). A [back-up power](#) system is recommended.

Mains-powered CR-FR are typically connected to an optional [back-up power](#) system that includes a standby generator. An [SDD](#) CR-FR may utilize a reliable mains or a standby generator (DC or AC) for [back-up power](#). A solar plus battery system is not an acceptable [back-up power](#) system in order to avoid reliance on large battery systems.

For mains [back-up power](#) a voltage stabilizing and surge protection system is required. All electrical and electronic components including temperature monitoring and alarm devices must be compatible with voltage stabilizers that use servo-mechanical or tap-changing technology. The preferred option is that this equipment should be supplied as part of the cold room/freezer room installation package.

For standby generator systems the minimum fuel capacity should be sufficient for at least 72 hours continuous running.

4.5.3 *Energy harvest control (optional):*

[Energy harvest control](#) (EHC) is an option and is an acceptable means for directly powering non-essential cooling [loads](#) and / or recharging battery-supported secondary [loads](#) (e.g., communications, and lighting). Battery storage is not acceptable for powering the essential cooling system and CR-FR electrical resistance heating elements, if included.

All [EHC](#) must comply with **WHO/PQS/E001/SDD CR-FR-VP.1** Test 4 that requires compliance with **WHO/PQS/E007/EHC01.1: Solar direct drive surplus energy harvest control** and testing per **WHO/PQS/E007/EHC01 VP.1: Solar direct drive surplus energy harvest. Control – Type examination protocol**.

4.6 Human factors:

4.6.1 *Generally:*

The product, its controls and temperature monitoring equipment must be useable by the widest practicable range of active health workers, regardless of age, gender, size or minor disability, including people with minor uncorrected vision, in accordance with the general principles laid out in ISO 20282-1: 2006.

4.7 Materials:

4.7.1 *Refrigerant:*

Refrigerants with zero ozone-depletion potential (ODP) are required and preference will be given to CR-FR that use gases with low global warming potential (GWP ≤ 11). The suitability of alternative refrigerant gases will continue to be assessed.

4.7.2 *Thermal insulation foaming agents:*

Any gas complying with the limitations and deadlines set by the [Montreal Protocol](#) and [Kigali Amendment](#) on the elimination of ozone-depleting chemicals with global warming potential (GWP) ≤ 11 and zero ozone depletion potential (ODP) must be clearly specified, labelled on the cooling equipment and used.

4.7.3 *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).

4.8 Warranty:

[Installations](#) are to be covered by a five-year on-site replacement warranty in the event of any component failure arising from defective design, materials or workmanship. The SDD power systems must comply with additional warranty requirements specified in **WHO/PQS/E003/PV01** or **WHO/PQS/E001/PVAC**. If included, an [EHC](#) system must comply with the warranty requirements specified in **WHO/PQS/ E007/EHC01.1** including batteries (if required). All warranty rights are to pass from the approved [installer](#) to the [employer](#) after the [installation](#) has been commissioned and has been formally accepted by the [employer](#). Where the [employer](#) is a UN agency,

the warranty rights are to pass to the host government². Provide commitment and quote for comprehensive maintenance contract for 2 years after the 5 years under warranty.

4.9 Servicing provision:

Installations are to be designed to achieve a service life of not less than 20 years apart from routine cleaning and programmed maintenance.

4.10 Disposal and recycling:

The manufacturer is to provide information to the buyer on the hazardous materials contained within the installation and suggestions 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.

4.11 Instructions:

Every cold room or freezer room must be accompanied by a comprehensive package of printed instruction material as described in clauses 4.11.1, 4.11.2 and 4.11.3. The documentation must be installation-specific and supplied bound or in loose leaf format in lever arch files. Instructions must be in the UN language most appropriate to the installation site; Arabic, English, French, Mandarin Chinese, Russian or Spanish. The printed material may be supplemented by memory sticks, CDs or DVDs in the same language.

4.11.1 *Installation instructions:*

Provide a comprehensive, illustrated step-by-step installation manual suitable for use by the **installer**, covering the unpacking, assembly, testing and commissioning of all the system components, including safe working procedures to be observed. The manual must be supplied in triplicate - one copy for the **employer**, one for the **installer** and one for the **maintenance contractor**.

4.11.2 *Service instructions:*

Provide a comprehensive, illustrated service and workshop manual, suitable for use by the **maintenance contractor**, covering all the system components, including safe working procedures to be observed. The manual must be supplied in duplicate - one copy for the **employer** and one for the **maintenance contractor**.

4.11.3 *User instructions:*

Provide 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. The manual must be supplied in triplicate - one copy for the **employer**; one for the **maintenance contractor** and one to be kept near the main door of the cold room in a pocket provided.

The user manual to include at least the following:

- health and safety procedures, both for the CR-FR and for the power supply system;

² Some installations will initially be purchased by one of the UN procurement agencies. In this situation, warranty rights must pass to the host government or **user** organization.

- compatible types of voltage stabilizer or equivalent protection systems as applicable;
- basic operation, [cool-down time](#) and temperature adjustment (if applicable);
- vaccine storage instructions;
- simple daily, weekly and monthly maintenance tasks to be recorded in a provided logbook to be kept with the user manual;
- method for defrosting;
- periodic preventative maintenance checks;
- diagnostic (trouble shooting) and repair procedures both for the CR-FR [installation](#) and for the power supply system(s);
- 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:

If specifically required, provide a practical hands-on training course for installers and/or maintenance technicians. The course may be conducted in-country or at the [legal manufacturer's](#) own workshop.

4.13 Verification:

[SDD](#) CR or FR will be required to successfully comply with **WHO/PQS/E001/SDD CR-FR VP.1** including a series of performance tests in a controlled environment.

Prior to prequalification each unique model of [SDD](#) CR-FR must complete a pre-approved WHO PQS field evaluation per the **Generic Guide for the Field Evaluation of New Technologies for WHO PQS Prequalification**. After acceptable field evaluation additional models of different volumes that utilize the same components as a fully prequalified [SDD](#) CR-FR will be required to comply with **WHO/PQS/E001/SDD VP.1** but will not be required to undergo further field evaluation.

If an [energy harvesting control \(EHC\)](#) system is part of the [SDD](#) WICR/FR the [EHC](#) must meet the specifications described in **WHO/PQS/E007/EHC01.1** and pass the verification protocol described in **WHO/PQS/E007/EHC01 VP.1**.

Pre-qualification evaluation of the system components and the offered installation and maintenance services will be carried out in accordance with PQS type examination protocol **WHO/PQS/E001/SDD CR-FR-VP.1**. Post-tender assessment and field commissioning of [installations](#) incorporating pre-qualified components will be carried out in accordance with PQS quality assurance protocol **WHO/PQS/E001/SDD CR-FR-VP2**.

5. **Packaging:**

Materials used for packaging the [installation](#) components are to be free of ozone-depleting compounds as defined in the [Montreal Protocol](#). The general specification of shipping containers will be subject to agreement with the individual procurement agencies and/or the [employer](#).

6. On-site installation:

The supplied components will be installed, tested and commissioned by an [installer](#) working to the instructions supplied by the manufacturer.

7. Product dossier:

The [legal manufacturer](#) or [reseller](#) is to provide WHO with a pre-qualification dossier containing the following:

General information:

- Dossier examination fee in US dollars.
- General information about the [legal manufacturer](#), including name and address.
- General information about the [reseller](#), including name and address (where applicable).
- Details of the [region\(s\)](#) for which pre-qualification is sought accompanied by evidence that the [legal manufacturer](#) or [reseller](#) can support deliveries to these [region\(s\)](#).
- A minimum of six references from separate clients in at least three separate countries. References must be no more than three years old and must include at least three references for the supply of CR-FR and three references for the supply of [SDD](#) power systems.

Technical details:

- Confirm the cold room size(s) that are being offered.
- Confirm the freezer room size(s) that are being offered.
- Confirm the solar direct drive power system specifications including solar module, solar array, system operating voltage, and, if required, the [EHC](#) including [EHC](#) powered [loads](#) required for operation of the CR-FR.
- Full specifications, photographs and technical details of the individual components (excluding temperature monitoring systems) of the CR-FR and [SDD](#) and [EHC](#) sufficient to demonstrate compliance with all the requirements set out in this document, including details of product marking and traceability.
- List of the temperature monitoring systems, already pre-qualified under PQS section E006, which will be offered as part of the package.

Norms and standards:

- Certified copies of all type-approvals obtained for the individual components, including CE marking and the like.
- Certified copies of the [legal manufacturer](#) or [reseller's](#) **ISO 9001** quality system certification.
- Certified photocopies of the [legal manufacturer](#) **ISO 14001** certification, [EMAS](#) registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is mandatory.
- Where available, laboratory test report(s) proving conformity with the product specifications.

Standard documentation:

- A complete sample set of the proposed [installation](#), service and user instructions.
- Details of the optional practical training course and confirmation of the location(s) where this can be conducted.
- A copy of the company's standard warranty agreement (clause 4.8).

Spare parts:

- Confirmation of the lead times for commonly required spare parts, including refrigeration units and the like.

8. On-site maintenance:

The employer will generally contract with a local [maintenance contractor](#) to undertake long-term maintenance of the [installation](#). The recommended terms for such an agreement include the following response rate:

- If one refrigeration unit fails the defective unit or component must be repaired or replaced within six days.
- If both refrigeration units fail, at least one refrigeration unit must be repaired or replaced within 24 hours. The second unit must be repaired or replaced within six days.
- If the [SDD](#) power system fails it must be repaired or replaced within six days.
- If both the [SDD](#) power system and the back-up power system fail at least one power system must be repaired or replaced within 24 hours. The second power system must be repaired or replaced within six days.
- Ancillary components such as alarms and thermometers must be replaced within six days.

Maintenance contractors must be assured that they can obtain spare parts from the manufacturer or his agent in time to meet these response criteria.

9. Change notification:

The [legal manufacturer](#) or [reseller](#) is to advise WHO [in writing](#) of any changes which adversely affect the performance of the product after PQS pre-qualification has taken place.

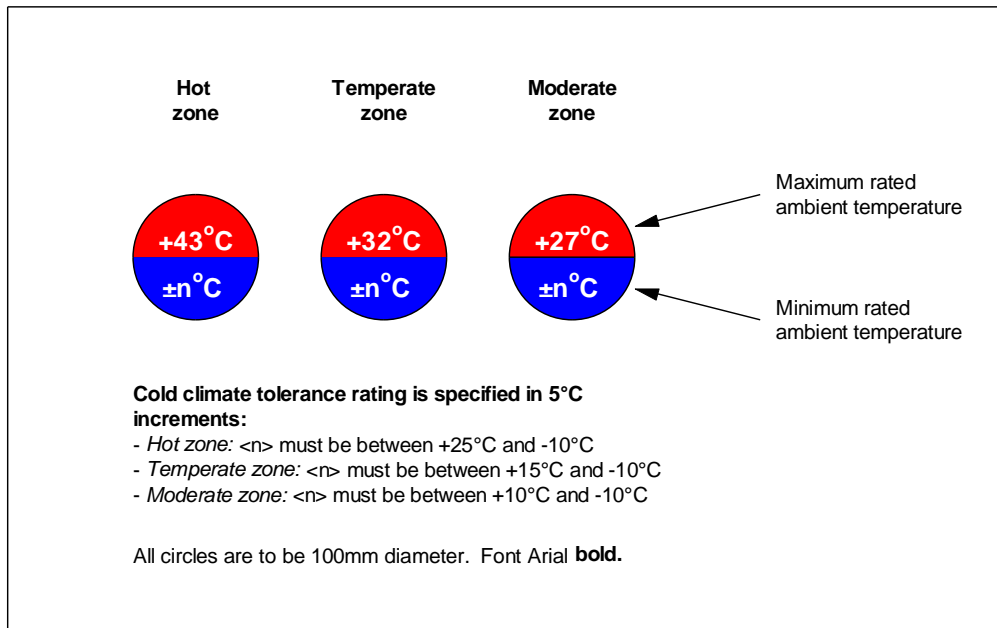
10. Defect reporting:

The [legal manufacturer](#) or [reseller](#) is to advise WHO and the UN purchasing agencies [in writing](#) in the event of safety-related product recalls, component defects and other similar events within 30 days after the first known event. If requested to do so by WHO or UNICEF, the manufacturer must 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.

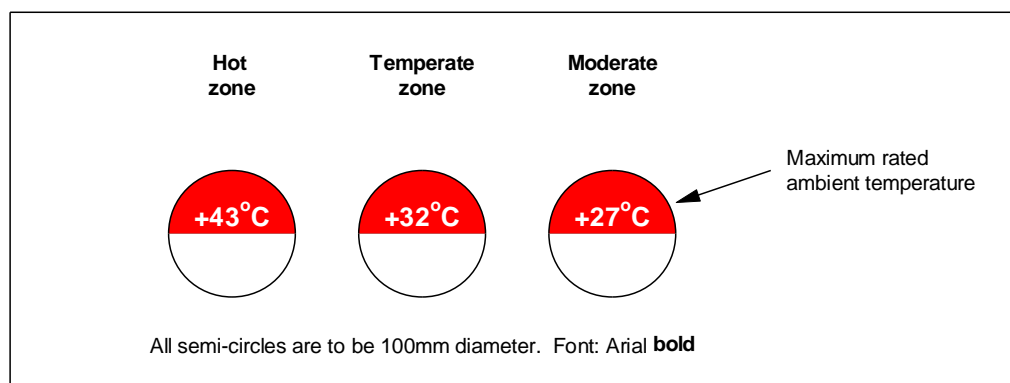
Annex 1 – Temperature zone symbols

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



Revision history:			
Date	Change summary	Reason for change	Approved