TITLE: Cold rooms and freezer rooms

Specification reference:	E01/CR-FR01.2
Product verification protocol:	E01/CR-FR01-VP1.2 and E01/CR-FR01-VP2.2
Date of origin:	02.08.2007
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Contents:

1. Scope:

E01/CR-FR01 describes the performance requirements for a generic cold room or freezer room installation, with packaged cooling units, suitable for storing vaccine. It also specifies the installation and maintenance advisory services that all manufacturers must offer in order to become pre-qualified. It applies to rooms up to a gross internal cubic capacity of $40m^3$.

The following documents are associated with this specification.

- **E01/CR-FR01-VP1** is a type-examination protocol which will be used for pre-qualification evaluations.
- **E01/CR-FR01-VP2** is completed by an employer or his QA assessor and sets out the requirements for a specific installation. The document also specifies the installation, commissioning and handover procedure. The completed protocol should be read in conjunction with **E01/CR-FR01**, to which it refers.

E01/CR-FR01 and a completed **E01/CR-FR01-VP2**, 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. The also forms the basis for a contractual agreement between the employer and the approved installer.

2. Normative references:

EMAS: *European Union Eco-Management and Audit Scheme.*
IEC 60335-1: 2006 – *Safety of household and similar electrical appliances, Part 1: General requirements.*

IEC 60364-1: 2005 – *Low-voltage electrical installations – Part 1: Fundamental principles, assessment of general characteristics, definitions.*
ISO 9001: 2008: *Quality Management Systems – Requirements.*
ISO 14001: 2004: *Environmental management systems – Requirements with guidance for use.*
ISO 20282-1: 2006: *Ease of operation of everyday products – Part 1: Context of use and user characteristics.*
WHO/PQS/E06/TH02.1: *Fixed gas or vapour pressure dial thermometer.*
WHO/PQS/E06/TR03.1: *Programmable electronic temperature and event logger systems with integral alarm and auto-dialer options.*
WHO/PQS/E06/TR03-VP2.1: *Programmable electronic temperature and event logger systems with integral alarm and auto-dialer options – Quality Assurance protocol.*
WHO/PQS/E06/TR04.1: *Wall-mounted pen recording thermometer.*
WHO/PQS/E06/TR05.1: *User-programmable temperature data loggers.*
WHO/PQS/E01/CR-FR01-VP1.2: *Cold rooms and freezer rooms – Type-examination protocol.*
WHO/PQS/E01/CR-FR01-VP2.2: *Cold rooms and freezer rooms – Quality Assurance protocol.*

3. Terms and definitions:

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.
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 of -10°C.
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.
Holdover time: The time in hours during which:

- **Cold room:** All points remain between +2°C and +10°C after the power supply has been disconnected when the room is exposed to the maximum ambient temperature for which it is designed. In the case of a cold room with cold climate freeze prevention, holdover time is also measured at the minimum ambient temperature specified by the employer.
- **Freezer room:** All points remain below -10°C after the power supply has been disconnected when the room is exposed to the maximum ambient temperature for which it is designed.

Hot zone: Hot zone units must operate at a steady +43°C ambient temperature and over a+43°C/+25°C day/night cycling temperature range.
Installation: The complete cold room or freezer room installation specified in this document.
Installer: A person or organization who has been appointed by the employer to carry out the installation of the system.
In writing: means 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.
Maintenance Contractor: A person or organization contracted by the employer to maintain the installation.
Moderate zone: Moderate zone units must operate at a steady +27°C ambient temperature and over a+27°C/+10°C day/night cycling temperature range.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
QA Assessor: the person or 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.
QA: Quality Assurance.
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.
Temperate zone: Temperate zone units must operate at a steady +32°C ambient temperature and over a +32°C/+15°C day/night cycling temperature range.
User: The person responsible for the day to day operation and temperature monitoring of the 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 he is 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. Manufacturers may offer products suitable for one or more temperature zones and may restrict their offer to one or more named regions.

4.1.2 Extended region pre-qualification

A pre-qualified manufacturer who wishes to extend the region(s) for which he is already pre-qualified may do so at the time of the annual review by providing WHO with supplementary evidence in writing that he is able to offer the complete service described in this specification to the additional region(s).

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. It must be possible, using these components, to install and to maintain a wide range of

different sized installations with a maximum individual room capacity of 40m^3. Rooms larger than this may be required, but are not included in the scope of this specification and will be subject to special arrangement between the manufacturer and the employer.

4.2.2 Temperature zones:

Provide hot zone, temperate zone or moderate zone equipment as required for a specific installation. 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. 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 ± 0.5°C or better.

- **Cold room:** Room temperature must remain between +2°C to +8°C when measured in any part of the room, 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.
- **Freezer room:** Room temperature must remain between -25°C to -15°C when measured in any part of the room, 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).

4.2.4 Holdover time:

In the event of a power failure at the maximum operating temperature for the specified temperature zone, all points in the room where vaccine is designed to be stored must remain within the limits stated below for a minimum period of eight hours when the room is empty.

- **Cold room:** Between +2°C and +10°C. In the case of a cold room with cold climate freeze prevention the minimum holdover time must also be achieved at the lowest ambient temperature at which the room is designed to operate.
- **Freezer room:** Below -10°C.

4.2.5 Electrical safety rating:

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 IEC 60364-1.

4.2.6 Voltage, frequency and phasing:

Depending on the size of the enclosure, the following options are to be offered:

- **Single –phase:** 220-240 volt 50/60 Hz and 100-127 volt 50/60 Hz single-phase.
- **Three-phase:** 190-240 volt 50/60 Hz and 380-480 volt 50/60 Hz three-phase.

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 Panel insulation:

In moderate zones the thermal transmittance (U value) of the roof, wall and floor panels must be 0.25 W/m²K or better. In temperate zones the thermal transmittance (U value) of the roof, wall and floor panels must be 0.20 W/m²K or better. In hot zones the thermal transmittance (U value) of the roof, wall and floor panels must be 0.17 W/m²K or better. Foam insulation must comply with clause 4.7.2.

4.2.9 Panel construction:

Panels must be made from zinc coated steel sheet, fully insulated, without internal structural members or stiffeners between the skins. Tongued and grooved joints between panels must be designed to minimize cold-bridging. Gaskets are to be resistant to damage from oil, fats, water and detergents. Floor panels must to have a hard-wearing non-slip finish. Wall and roof panels must have a white plastics coating.

4.2.10 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 to ensure that there is no risk that vaccine stored on the cold room side of the wall will be exposed to temperatures below +2°C, or that vaccine stored on the freezer room side of the wall will be exposed to temperatures above -15°C.

4.2.11 Door construction:

Doors must be constructed and insulated to the same standard as clause 4.2.9. Doors must be lockable with 100% fail-safe provision for opening from inside. The clear opening width of the door must be 600mm minimum for rooms up to 10 cubic metres and at least 800mm minimum for larger rooms. Provide an internal clear plastic strip curtain.

4.2.12 Door frame heating element:

Provide a door frame heating element for all freezer rooms and for cold rooms in humid climates.

4.2.13 Pressure relief valve (freezer rooms only):

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

4.2.14 Heater mat (freezer rooms only):

If required, provide an electric resistance heater mat, with thermostatic control, to prevent frost heave (ground floor location) or ceiling condensation (upper floor location) below freezer room floor panels.

4.2.15 Shelving:

Wall-mounted or free-standing stove enamelled steel, galvanized steel, stainless steel, aluminium or plastic slatted adjustable shelving units to carry vaccine in packages. Slatted shelves are preferred. Shelves must be not less than 450mm and not more than 600mm deep at approximately 450mm vertical centres. The top face of the lowest shelf must be mounted 200mm above the floor. Each shelf must be rated to support at least 0.075 kg/cm². The span between supports must be 1.0 metres or less. Shelving must be washable.

4.2.16 Refrigeration units:

Packaged refrigeration units with single-phase or three- phase compressors, sized to give 100% stand-by capacity under worst-case conditions. Refrigerants must comply with clause 4.7.1. There must be a timer operated electric or hot-gas defrosting system and a condensate drip tray and drain

connection. Provide an automatic duty-sharing circuit with seven-day changeover and manual override in event of mechanical failure. Provide protection against high or low voltage and against cycle fluctuations. There must be an automatic cut-out when conditions are outside the cold room manufacturer's defined safe limits and an automatic cut-in within 6 minutes of the restoration of safe conditions. Depending upon the internal room layout and the room location, units may be arranged in the following ways:

- **Either:** Units may be wall-mounted with the condenser unit discharging inside the building that houses the cold room.
- **Or:** Evaporator units may be wall-mounted with a weatherproof condenser unit mounted externally (split unit).
- **Or:** Units may be ceiling-mounted with a condenser unit discharging inside the building that houses the cold room.
- **Or:** Evaporator units may be ceiling-mounted with a weatherproof condenser unit mounted externally (split unit).

4.2.17 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 is clear of shelving units. If necessary provide a removable mesh cage or deflector shield around the evaporator so as to maintain the safe storage zone.

4.2.18 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 the temperature specified by the employer, at the time of procurement, subject to a minimum of
-10°C.

4.2.19 Lighting:

Provide internal ceiling-mounted tungsten filament lighting with an external switch and pilot light. The 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.
Note: Fluorescent lighting damages certain vaccines and must not be used.

4.2.20 Alarm system:

Provide a mains-operated audible alarm with battery backup and automatic recharge, which is triggered in the event of mains failure or when freezer room temperatures are outside set limits. The alarm must comply with PQS specification **E06/AL01,** or with **E06/TR03** if a component part of an event logger system. Alarm sounder repeaters are to be located adjacent to the cold room/freezer room and at one remote location.

4.2.21 Temperature recording:

As required for the specific installation, provide:

- **Either:** A 7-day wall-mounted pen recording thermometer complying with **PQS EO6/TR04** fitted with alarm contacts and door-open sensor and linked to the alarm system specified in clause 4.2.19.
- **Or:** A programmable electronic temperature and event logger system with auto-dialer complying with **PQS E06/TR03** linked to the alarm system specified in clause 4.2.19.

In both cases, provide a backup gas or vapour pressure dial thermometer complying with **PQS E06/TH02**, mounted on the wall of the cold room in an accessible position.

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

4.2.23 Spare parts:
Provide spare parts sufficient for five years of normal operation at the specified location(s).

4.3 *Environmental requirements:*

4.3.1 Ambient temperature range during transport and storage:
-30°C to +55°C when components are in transit.

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

4.4 *Physical characteristics:*

4.4.1 Room capacity:
Individual rooms, not exceeding 40m^3 each, and which may form part of a multi-room assembly.

4.4.2 Overall dimensions:
Individual components must generally be able to fit through an 800mm 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 safely manhandled into their final positions. Mechanical lifting equipment will typically not be available at the installation sites.

4.5 *Interface requirements:*

4.5.1 Voltage stabilizer compatibility:
Voltage stabilization and surge protection will generally be required for cold rooms and freezer room installations. All electrical components 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.

4.5.2 Standby generator:
Cold rooms and freezer rooms are typically connected to a standby generator. This will either be installed already, or it will be supplied by others. The design of each specific installation must be coordinated with the standby generator installer.

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 long-sighted people without glasses, in accordance with the general principles laid out in ISO 20282-1: 2006.

4.7 *Materials:*

4.7.1 Refrigerant:

CFC-free to comply with the requirements of the Montreal Protocol. Flammable refrigerants are not acceptable. The casing and/or the compressor body of each refrigeration unit must carry a permanent label clearly identifying the refrigerant used in letters not less than 10mm high.

4.7.2 Thermal insulation foaming agents:

Any gas complying with the limitations and deadlines set by the Montreal Protocol on the elimination of ozone-depleting chemicals.

4.7.3 Other restricted materials:

The product and its constituent components, including 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 three year on-site replacement warranty in the event of any component failure arising from defective design, materials or workmanship. All warranty rights are to pass from the approved installer to the employer after the installation has been commissioned and has been formally acc12epted by the employer. Where the employer is a UN agency, the warranty rights are to pass to the host government[1].

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 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

[1] Some installations will initially be purchased by one of the UN procurement agencies. In this situation, warranty rights must pass to the host government.

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 duplicate - one copy for the employer and one for the maintenance contractor.

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 manufacturer's own works.

4.13 *Verification:*

Pre-qualification evaluation of the system components and the offered installation and maintenance services will be carried out in accordance with PQS Verification Protocol **E01/CR-FR01-VP1.2**. Post-tender assessment and field commissioning of installations incorporating pre-qualified components will be carried out in accordance with PQS Verification Protocol **E01/CR-FR01-VP2.2**.

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 five references from separate clients in at least three separate countries. References must be no more than three years old.

Technical details:

- Confirm the cold room sizes that are being offered.
- Confirm the freezer room sizes that are being offered.
- Full specifications, photographs and technical details of the individual components (excluding temperature monitoring systems) 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 E06, which will be offered as part of the package.

Norms and standards:

- Certified photocopies of all type-approvals obtained for the individual components, including CE marking and the like.
- Certified photocopies of the legal manufacturer or reseller's ISO 9001 quality system certification.
- Where relevant, certified photocopies of the legal manufacturer or reseller's ISO 14001 certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- 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 seven 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 seven days.
- Ancillary components such as alarms and thermometers must be replaced within seven 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:

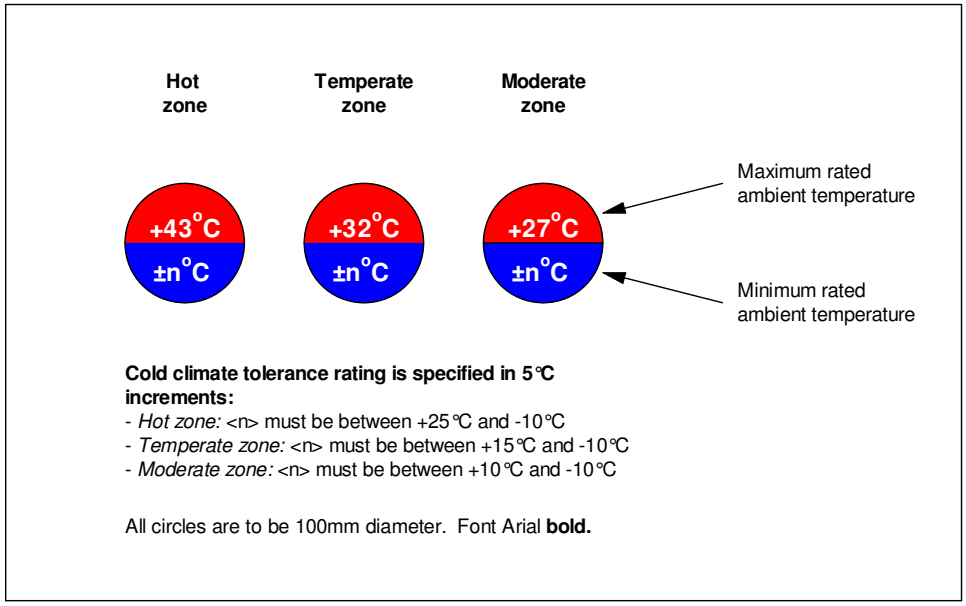
The legal manufacturer or reseller is to advise WHO in writing of any changes which adversely affect the performance of the product after PQS pre-qualification has taken place.

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.

Annex 1 – Temperature zone symbols

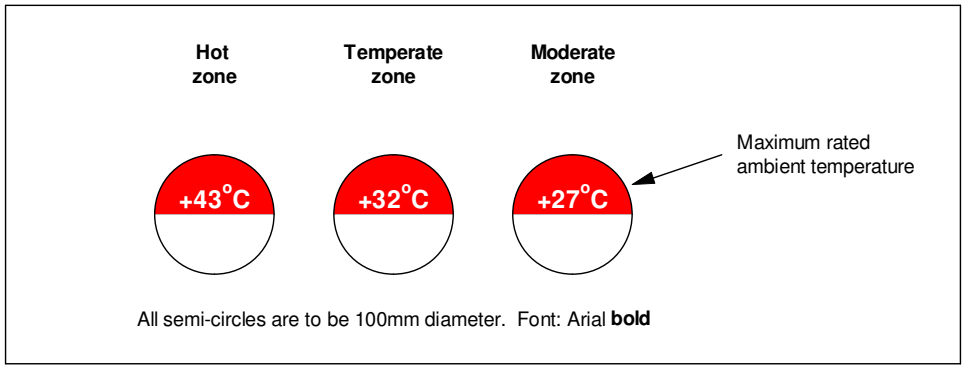
Cold room symbols



Cold climate tolerance rating is specified in 5°C increments:
- *Hot zone:* <n> must be between +25°C and -10°C
- *Temperate zone:* <n> must be between +15°C and -10°C
- *Moderate zone:* <n> must be between +10°C and -10°C

All circles are to be 100mm diameter. Font Arial **bold.**

Freezer room symbols



All semi-circles are to be 100mm diameter. Font: Arial **bold**

Revision history:			
Date	Change summary	Reason for change	Approved
20.03.2007	Updated and re-drafted in PQS format	Compatibility with PQS.	
09.05.2007	Revised to SMc comments & teleconference UK, SMc, AG 26.04.07		
16.05.2007	Final review version		
02.08.2007	Final version – no changes.		
28.01.2009	Major general revision eliminating manufacturer-approved installers and maintenance contractors. 1: amended. 2: Normative references updated. 3: definitions changed. 4.1.1: redrafted 4.1.2: redrafted 4.2.13: wall-mounted vents allowed 4.2.15: plastic shelving added; shelf loading amended. 4.11: redrafted 4.12: redrafted 6: redrafted 7: amended 8: amended	Response to manufacturer comments.	