



TITLE: Cold rooms and freezer rooms

<i>Product verification protocol:</i>	E01/CR-FR01-VP1.1
<i>Applies to specification ref(s):</i>	E01/CR-FR01.1
<i>Date of origin:</i>	02.08.2007
<i>Date of last revision:</i>	New protocol

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1. Scope:

E01/CR-FR01-VP1 is a type-examination protocol which will be used for the pre-qualification evaluation of cold rooms and freezer room manufacturers.

It should be read in conjunction with **E01/CR-FR01** which describes the performance requirements for a generic cold room or freezer room [installation](#), with packaged cooling units, suitable for storing vaccine. The document also specifies the installation and maintenance service that all manufacturers must offer in order to become pre-qualified. It applies to rooms up to a gross internal cubic capacity of 40m³.

A second verification protocol, **E01/CR-FR01-VP2** completes the package. This document is completed by an [employer](#) or his [QA assessor](#), setting out the requirements for a specific installation. The document also sets out the installation, commissioning and handover procedure. The completed protocol should also 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 [legal manufacturer](#) or [reseller](#) and the [employer](#) for the supply, installation and commissioning of a specific [installation](#).

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: 2000: *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/E06/CR-FR01.1: *Cold rooms and freezer rooms*.
WHO/PQS/E06/CR-FR01-VP2.1: *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.

Approved Installer: A person or organization approved by the [legal manufacturer](#) or [reseller](#) as a competent installer of the pre-qualified components, and who has been appointed by the [employer](#) to carry out the [installation](#).

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 [approved installer](#) to carry out installation and commissioning.

Evaluator: An individual or organization (including a testing laboratory) responsible for evaluating the suitability of the components and services described in this specification for inclusion in the register of PQS pre-qualified products.

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 an ambient temperature of -10°C.

- **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.

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 approved by the **legal manufacturer** or **reseller** as competent 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 **approved installers**, to evaluate their proposals and to monitor the installation and commissioning of the installation on site.

QA: Quality Assurance.

Region: A contiguous geographical area within which the **legal manufacturer** or **reseller** is able to provide the full range of services describe in specification **E01 CR-FR01**.

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. **Applicability:**

Type-examination will be carried out by an independent **evaluator**, appointed by WHO. The extent of the geographical limits of any grant of pre-qualification status will be reviewed and decided upon by WHO.

5. **Sample-examination checklist:**

5.1 *Evidence of conformity assessment:*

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

5.2 Samples and supporting material:

The **Legal Manufacturer** or **Reseller** must supply the **evaluator** with a full duplicate set of the Product Dossier already supplied to WHO in accordance with the requirements of specification clause 7. In addition, demonstration samples are to be supplied, as follows:

- Paired wall panel samples showing insulation, finishes, joint construction, and panel locking arrangement;
- Paired roof panel samples showing insulation, finishes, joint construction and panel locking arrangement (if different from wall panels);
- Paired floor panel samples showing insulation, finishes, joint construction and panel locking arrangement;
- Shelf sample, including support system.
- If alternative panel finishes are available, provide small samples.
- JPEG image of a typical installation for possible inclusion in the PQS data sheet.

5.3 Type-examination procedure:

- **Step 1:** Check all demonstration samples for similarities between different models¹, dissimilarities between samples of one model, and any defects or damage.
- **Step 2:** Record any differences between the samples ordered and those received.
- **Step 3:** Complete the compliance checklist in Annex 1. Record general comments and recommendations for each section.
- **Step 4:** Take a three quarter view digital photograph of each of the demonstration samples.
- **Step 5:** Obtain any additional supporting information required **in writing** from the **Legal Manufacturer** or **Reseller** and attach this information to the report.

Acceptance criteria: Inspection indicates full conformity with all major specification requirements, subject to acceptable restrictions on temperature zones² and region(s).

5.4 Criteria for qualification:

A final report must be issued after the type-examination is complete. The report must contain the following data and analyses:

Summary: Conclusions and recommendations.

Compliance checklist: Completed Annex 1 checklist.

Photographs: Photographs of samples.

Temperature zone(s): Assessment of the temperature zone(s) for which the product is suitable.

¹ The purpose of this inspection is to establish whether products offered by competing companies are re-badged versions of an otherwise identical product.

² 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 must be excluded from the pre-qualification listing.

Region(s) Assessment of the [region\(s\)](#) within which the product should be pre-qualified.

Annexes: Additional supporting documentation requested and received from the [Legal Manufacturer](#) or [Reseller](#) during the course of the type-examination.

6. Quality control checklist:

6.1 Quality control standards:

All reporting must be carried out in accordance with the requirements of this document.

6.2 Quality control checklist:

An on-site inspection of the manufacturing plant is not required.

7. Pre-qualification evaluation:

An applicant company will qualify for inclusion on the register of PQS pre-qualified cold rooms and freezer room suppliers, in accordance with WHO procedures, provided the final report indicates that cold room and freezer rooms supplied, installed and maintained by the company are likely to be able to achieve full conformity with the requirements of specification **E01 CR-FR01** and verification protocol **E01 CR-FR01-VP2** 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 affect the performance of the product. WHO will carry out a desk evaluation of the reported change(s). If any change is deemed adversely to affect the performance of the product, WHO may request full or partial re-verification based on the type-examination procedures described in this document.

Annex 1 – Compliance checklist³

Spec clause	Item	
A. General information:		
7.	Dossier fee received:	Yes <input type="checkbox"/> No <input type="checkbox"/> Part payment <input type="checkbox"/>
7.	Type-examination fee received:	Yes <input type="checkbox"/> No <input type="checkbox"/> Part payment <input type="checkbox"/>
7.	Legal Manufacturer details: Name: Address 1: Address 2: Address 3: Address 4: Tel: Fax: Email: Web:	
7.	Reseller details: Name: Address 1: Address 2: Address 3: Address 4: Tel: Fax: Email: Web:	Applicable <input type="checkbox"/> Not applicable <input type="checkbox"/>
7.	Status: Legal Manufacturer Reseller	<input type="checkbox"/> <input type="checkbox"/>
7.	No. of regions:	
7.	Region 1 description:	
7.	Region 1, Country 1:	Approved installer? Yes <input type="checkbox"/> No <input type="checkbox"/> Maintenance contractor? Yes <input type="checkbox"/> No <input type="checkbox"/> Completed installations? None <input type="checkbox"/> Client reference received? Yes <input type="checkbox"/> No <input type="checkbox"/>
7.	Region 1, Country 2:	Approved installer? Yes <input type="checkbox"/> No <input type="checkbox"/> Maintenance contractor? Yes <input type="checkbox"/> No <input type="checkbox"/> Completed installations? None <input type="checkbox"/> Client reference received? Yes <input type="checkbox"/> No <input type="checkbox"/>
7.	Region 1, Country 3:	Approved installer? Yes <input type="checkbox"/> No <input type="checkbox"/>

³ This is a Word 'Form' document. It needs to be copied and 'protected' before it can be used for data entry. Then activate View/Toolbars/Forms and click the 'lock' icon on the Forms toolbar. See also Word Help. Margins can be adjusted so form fits on a single page.

Spec clause	Item	
		Maintenance contractor? Yes <input type="checkbox"/> No <input type="checkbox"/> Completed installations? None <input type="checkbox"/> Client reference received? Yes <input type="checkbox"/> No <input type="checkbox"/>
7.	Region 1, Country 4:	Approved installer? Yes <input type="checkbox"/> No <input type="checkbox"/> Maintenance contractor? Yes <input type="checkbox"/> No <input type="checkbox"/> Completed installations? None <input type="checkbox"/> Client reference received? Yes <input type="checkbox"/> No <input type="checkbox"/>
7.	Region 1, Country 5:	Approved installer? Yes <input type="checkbox"/> No <input type="checkbox"/> Maintenance contractor? Yes <input type="checkbox"/> No <input type="checkbox"/> Completed installations? None <input type="checkbox"/> Client reference received? Yes <input type="checkbox"/> No <input type="checkbox"/>
Replicate cells as necessary for additional countries and regions ↑		
<i>General information comments:</i>		
B. Technical details:		
7.	Cold room sizes:	
7.	Freezer room sizes:	
4.2.2	Temperature zones	Hot zone compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Temperate zone compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Moderate zone compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Cold climate freeze prevention compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.3	Temperature control	Cold room temperature control acceptable? Yes <input type="checkbox"/> No <input type="checkbox"/> Freezer room temperature control acceptable? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.4	Holdover time	Cold room holdover time achievable? Yes <input type="checkbox"/> No <input type="checkbox"/> Freezer room holdover time achievable? Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Temperature control comments:</i>		
4.2.5	Electrical safety rating	Compliance with IEC 60335-1 certified? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.6	Voltage, frequency and phasing	List options offered: Options compatible with requested countries? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.7	Voltage stabilization and surge protection	Voltage stabilization offered? Yes <input type="checkbox"/> No <input type="checkbox"/> Surge protection offered? Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Electrical requirements comments:</i>		
4.2.8	Panel insulation	Panel insulation options offered: Hot zone compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Temperate zone compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Moderate zone compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.9	Panel construction	Panel construction(s) offered: Panel construction satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/> Joint construction satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/> Wall/roof panel finish satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/> Floor panel finish(es) satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.10	Shared walls	Shared wall construction(s) offered: Shared wall construction satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>

Spec clause	Item	
4.2.11	Door construction	Door construction(s) offered: Door construction satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/> Door size options satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/> Strip curtain offered? Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Panel and door construction comments:</i>		
4.2.12	Door frame heating element	Door frame heating element offered? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.13	Pressure release valve	Pressure release valve offered? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.14	Heater mat	Heater mat offered? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.15	Shelving	Shelving option(s) offered: Shelving construction satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/> Shelving size options satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Ancillary fittings comments:</i>		
4.2.16	Refrigeration units	Refrigeration unit option(s) offered: Refrigerant(s) satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/> Defrosting system satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/> Duty sharing system satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/> High/low voltage protection satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/> Cut-out system satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.17	Evaporator plume guard	Evaporator plume guard offered: Plume guard system satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.18	Cold climate protection	Freeze-protection system offered: Freeze-protection system satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Refrigeration unit comments:</i>		
4.2.19	Lighting	Lighting system offered: Lighting system satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.20	Alarm system	Alarm system(s) offered: Alarm systems PQS-compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.21	Temperature recording	Temperature recording system(s) offered: Temp recording systems PQS-compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Temperature monitoring, alarm and lighting comments:</i>		
4.4.2	Overall dimensions	Component sizes comply? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.4.3	Weight	Component weights comply? Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Dimension and weight comments:</i>		
4.7.1	Refrigerant	Refrigerants comply with Montreal Protocol? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.7.2	Foaming agents	Gas complies with Montreal Protocol? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.7.3	Other restricted materials	Restricted materials in system components? Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Refrigerant and materials comments:</i>		
C. Norms and standards:		
7.	Type approval details:	Details: Satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>
7.	Current ISO 9001: 2000 certification:	Satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>
7.	Environmental audit scheme	Type: Current? Yes <input type="checkbox"/> No <input type="checkbox"/> (Note: not mandatory)
7.	Laboratory test reports	Details:

Spec clause	Item	
<i>Norms and standards comments:</i>		
<i>D. Installation documentation:</i>		
-	Pre-installation documentation sample	Supplied? Yes <input type="checkbox"/> No <input type="checkbox"/> If 'yes' is it satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.8	Warranty agreement	Supplied? Yes <input type="checkbox"/> No <input type="checkbox"/> If 'yes' is it compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
8.	On-site maintenance agreement	Supplied? Yes <input type="checkbox"/> No <input type="checkbox"/> If 'yes' is it satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Documentation comments:</i>		
<i>E. Conclusions:</i>		
<i>Overall summary:</i>		
		DECISION: Pre-qualify? <input type="checkbox"/> Reject <input type="checkbox"/>

Revision history:			
Date	Change summary	Reason for change	Approved
20.03.2006	Original		UK
09.05.2007	Revised to SMC comments & teleconference UK, SMC, AG 26.04.07		UK
16.05.2007	Final review version		UK
02.08.2007	Final version – no changes.		UK