



TITLE: Cold rooms and freezer rooms

Product verification protocol: E01/CR-FR01-VP1.2

Applies to specification ref(s): E01/CR-FR01.2

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1. Scope:

E01/CR-FR01-VP1.2 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-FR01.2** 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 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 40m³.

A second verification protocol, **E01/CR-FR01-VP2.2** completes the package. This document is initially used by an employer or his QA assessor to describe 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-FR01.2**, to which it refers.

E01/CR-FR01.1 and a completed **E01/CR-FR01-VP2.2**, together with an employer's other documents, are intended to form the basis for a contractual agreement between the employer and the legal manufacturer or reseller for the supply of the components required for a specific installation. These

documents also forms the basis for a separate contractual agreement between the employer and the 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-FR01.2: *Cold rooms and freezer rooms*.
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 specification E01/CR-FR01.2. 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.

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.
- In writing:** means communication by letter, fax or email.
- Installation:** The complete cold room or freezer room installation specified in this document.
- Installer:** A person or organization has been appointed by the **employer** to carry out the **installation**.
- 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 **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 described in specification **E01/ CR-FR01.2**.
- 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.

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.

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.

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 **components** supplied by the company are likely to be able to achieve full conformity with the requirements of specification **E01 CR-FR01.2** and verification protocol **E01 CR-FR01-VP2.2** 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 <input type="checkbox"/> Reseller <input type="checkbox"/>
7.	No. of regions:
7.	Description of regions offered:
7.	Supporting evidence offered for inclusion of each region:
7.	Evidence satisfactory: Yes <input type="checkbox"/> No <input type="checkbox"/>
7.	No. of references: (minimum 5 from at least 3 separate countries)
7.	References satisfactory: Yes <input type="checkbox"/> No <input type="checkbox"/>
General information comments:	
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"/>

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	
		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"/>
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:

Spec clause	Item	
		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:
<i>Norms and standards comments:</i>		
D. Instructions, training, other documents		
4.11.1	Sample installation instructions	Supplied? Yes <input type="checkbox"/> No <input type="checkbox"/> If 'yes' is it satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.11.1	Sample service instructions	Supplied? Yes <input type="checkbox"/> No <input type="checkbox"/> If 'yes' is it satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.11.1	Sample user instructions	Supplied? Yes <input type="checkbox"/> No <input type="checkbox"/> If 'yes' is it satisfactory? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.12	Training	Offered? Yes <input type="checkbox"/> No <input type="checkbox"/> If 'yes' is proposal 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>		
E. Conclusions:		
<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		
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. 7: amended Annex 1: amended	Response to manufacturer comments.	