



TITLE: Cold rooms and freezer rooms

Product verification protocol: E001/CR-FR01-VP1.4
 Applies to specification ref(s): E001/CR-FR01.4
 Issue date: 31 August 2015
 Date of last revision: 28 January 2009

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1. Scope:

E001/CR-FR01-VP1.4 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 **E001/CR-FR01.4** which describes the performance requirements for a generic cold room or freezer room *installation*, suitable for storing vaccine, assembled using prefabricated insulated panels and packaged cooling units. 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 with a gross internal cubic capacity exceeding 10m³, housed within an existing building. Fully weather-proof cold rooms and freezer rooms are not covered.

A second verification protocol, **E001/CR-FR01-VP2.4** 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 **E001/CR-FR01.4**, to which it refers.

E001/CR-FR01.4 and a completed **E001/CR-FR01-VP2.4**, together with an *employer's* other documents, are intended to form the basis for a contractual agreement between the *employer* and the *legal manufacturer* or *reseller* for the supply of the components required for a specific *installation*. These documents also form the basis for a separate contractual agreement between the *employer* and the *installer*.

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.

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

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.

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/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/E001/CR-FR01.4: Cold rooms and freezer rooms.

WHO/PQS/E001/CR-FR01-VP2.4: Cold rooms and freezer rooms – Quality Assurance protocol.

Directive 2002/96/EC of the European Parliament and of the Council

Directive 2004/108/EC of the European Parliament and of the Council.

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 **E001/CR-FR01.4**. 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.

Hot zone: Hot zone units must operate at a steady $+43^{\circ}\text{C}$ ambient temperature and over a $+43^{\circ}\text{C}/+25^{\circ}\text{C}$ day/night cycling temperature range.

In writing: means communication by letter, fax or email.

Installation: The complete cold room or freezer installation described in **E001/CR-FR01.4** and in the companion **E001/CR-FR01-VP.4** document and any other employer's requirements documentation issued for a specific installation or installations. Including voltage stabilizers and standby generators where these are listed in the employer's requirements.

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 $+27^{\circ}\text{C}$ ambient temperature and over a $+27^{\circ}\text{C}/+10^{\circ}\text{C}$ 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 **E001/CR-FR01.4**.

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 $+32^{\circ}\text{C}$ ambient temperature and over a $+32^{\circ}\text{C}/+15^{\circ}\text{C}$ 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 examination will take place at the manufacturing site or at another agreed location¹. 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 made available for inspection, as follows:*

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

5.3 Type-examination procedure:

- **Step 1:** *Check all demonstration samples for similarities between different models², dissimilarities between samples of one model, and any defects or damage.*
- **Step 2:** *Record any differences between the samples requested and those shown or received.*
- **Step 3:** *Complete the compliance checklist in Annex 1. Record general comments and recommendations for each section.*

¹ *In the case of a **Reseller** for example, the inspection could take place at an order assembly site where components are brought together for consolidation and onward shipment to customers.*

² *The purpose of this inspection is to establish whether products offered by competing companies are re-badged versions of an otherwise identical product.*

- **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 zones³ 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.

Scope: Review of samples and construction options included in the type examination exercise, including a list of any that is specifically excluded.

Compliance checklist: Completed Annex 1 checklist.

Photographs: Photographs of samples and of a complete installation.

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. This must include a copy of the applicant's current ISO 9001 certificate, a copy of relevant CE certification and other conformity assessment certificates and, where applicable, a copy of the applicant's current ISO 14001 certificate.

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:

Although an on-site inspection of the manufacturing plant is not mandatory, the type examination must take place at a location where full scale components can be inspected.

7. **Pre-qualification evaluation:**

An applicant company will qualify 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 room components supplied by the company are likely to be able to achieve full conformity with the requirements of specification **E001 CR-FR01.4** and verification protocol **E001 CR-FR01-VP2.4** in the *region(s)* for which pre-qualification is sought.

³ 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.

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 checklist⁴

This checklist must be completed by the person appointed to carry out the pre-qualification assessment.

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.	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"/>

⁴ 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.

Spec clause	Item	
		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	Holdover improvement option(s) offered? Yes <input type="checkbox"/> No <input type="checkbox"/> If YES, describe system or components offered:
<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 available: Options compatible with regions offered? 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	List panel insulation options offered: 'U' value 0.25 W/m ² K or better? Yes <input type="checkbox"/> No <input type="checkbox"/> 'U' value 0.17 W/m ² K or better (hot zone) ⁵ ? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.9	Wall and roof panel construction	List panel construction(s) offered: Panel construction compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Joint construction compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Panel finish compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Mastic joint sealing compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.10	Floor construction	List floor panel finishes offered: Floor panel loading options: Type A: Yes <input type="checkbox"/> No <input type="checkbox"/> Type B: Yes <input type="checkbox"/> No <input type="checkbox"/> Type C: Yes <input type="checkbox"/> No <input type="checkbox"/> In-situ flooring possible: Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.11	Shared walls	List shared wall construction(s) offered: Shared wall construction(s) compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.12	Door construction	List door options offered: Single leaf hinged doors? Yes <input type="checkbox"/> No <input type="checkbox"/> Double leaf hinged doors? Yes <input type="checkbox"/> No <input type="checkbox"/> Sliding doors? Yes <input type="checkbox"/> No <input type="checkbox"/> Door construction(s) compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Door size options compliant? 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>		
4.2.13	Door frame heating element	Door frame heating element offered? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.14	Pressure release valve	Pressure release valve offered? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.15	Heater mat	Heater mat offered? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.16	Shelving	List type(s) of shelving offered: Shelving construction compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Load bearing capacity compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Shelving size options compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.17	Pallet racking	List type(s) of racking system offered: System compliant with EN standards? Yes <input type="checkbox"/> No <input type="checkbox"/>

⁵ 'U' values verified by calculation and/or manufacturer's certification.

Spec clause	Item	
		Corrosion protection compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Ancillary fittings comments:</i>		
4.2.18	Refrigeration units	Refrigeration unit option(s) offered: Monobloc wall-mounted? Yes <input type="checkbox"/> No <input type="checkbox"/> Split system wall-mounted? Yes <input type="checkbox"/> No <input type="checkbox"/> Split system for ventilated enclosure? Yes <input type="checkbox"/> No <input type="checkbox"/> High rise air distribution system offered? Yes <input type="checkbox"/> No <input type="checkbox"/> Refrigerant(s) compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Defrosting system compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Duty sharing system compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> High/low voltage protection compliant? Yes <input type="checkbox"/> No <input type="checkbox"/> Cut-out system compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.19	Evaporator plume guard	Describe evaporator plume guard offered: Plume guard compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.20	Cold climate protection	Describe freeze-protection system offered: Freeze-protection system compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Refrigeration unit comments:</i>		
4.2.21	Lighting	List lighting system(s) offered: Lighting system compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.22	Alarm system	List alarm system(s) offered: Alarm systems PQS-compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.2.23	Temperature recording	List 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: Compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
7.	Current ISO 9001: certification:	Compliant? 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.	Other standards	Type(s):
7.	Laboratory test reports	Details:
<i>Norms and standards comments:</i>		
D. Instructions, training, other documents		
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"/>
4.11.1	Sample installation instructions	Supplied? Yes <input type="checkbox"/> No <input type="checkbox"/> If 'yes' are they compliant? 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' are they compliant? Yes <input type="checkbox"/> No <input type="checkbox"/>
4.11.1	Sample user	Supplied? Yes <input type="checkbox"/> No <input type="checkbox"/>

Spec clause	Item	
	<i>instructions</i>	<i>If 'yes' are they compliant? Yes <input type="checkbox"/> No <input type="checkbox"/></i>
4.12	<i>Training</i>	<i>Hands-on installation training offered? Yes <input type="checkbox"/> No <input type="checkbox"/></i>
		<i>If 'yes' is training course compliant? Yes <input type="checkbox"/> No <input type="checkbox"/></i>
		<i>Hands-on maintenance training offered? Yes <input type="checkbox"/> No <input type="checkbox"/></i>
		<i>If 'yes' is training course compliant? Yes <input type="checkbox"/> No <input type="checkbox"/></i>
6	<i>On-site installation service</i>	<i>On-site installation service offered? Yes <input type="checkbox"/> No <input type="checkbox"/></i>
		<i>If 'yes' is service compliant? Yes <input type="checkbox"/> No <input type="checkbox"/></i>
8.	<i>On-site maintenance service</i>	<i>Is an on-site maintenance service offered? Yes <input type="checkbox"/> No <input type="checkbox"/></i>
		<i>If 'yes' is it compliant? Yes <input type="checkbox"/> No <input type="checkbox"/></i>
<i>Documentation comments:</i>		
E. Conclusions:		
<i>Overall summary:</i>		
		DECISION: <i>Pre-qualify?</i> <input type="checkbox"/> <i>Reject</i> <input type="checkbox"/>

Revision history:			
<i>Date</i>	<i>Change summary</i>	<i>Reason for change</i>	<i>Approved</i>
20.03.2006	<i>Original</i>		
09.05.2007	<i>Revised to SMC comments & teleconference UK, SMC, AG 26.04.07</i>		
16.05.2007	<i>Final review version</i>		
02.08.2007	<i>Final version – no changes.</i>		
28.01.2009	<i>Major general revision eliminating manufacturer-approved installers and maintenance contractors. 1: amended. 2: Normative references updated. 3: definitions changed. 7: amended Annex 1: amended</i>	<i>Response to manufacturer comments.</i>	
30.04.2012	<i>General update to include cold rooms larger than 40m³ and pallet-based mechanical load handling.</i>	<i>Increased demand for larger units.</i>	
31/08/2015	<i>Delete reference to pen recorder</i>	<i>Considered as obsolete</i>	<i>DM</i>