WHO/PQS/ E001/LWICR01.1-VP1.2 Guidance

PQS Quality Assurance protocol guidance

Original: English Distribution: General

TITLE: Large Walk-in Cold Rooms - guidance section

Product verification protocol: E001/LWICR01.1- VP1.2 Guidance

Applies to specification ref(s): E001/LWICR 01.1 Issue date: New 07/01/2022

Date of last revision: N/a

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How to use this document

This document contains guidance on the cold room contracting process. It should be read in conjunction with PQS Type Examination protocol **E001/LWICR01.1-VP2.2** which sets out the requirements for the procurement, installation, commissioning, user training and subsequent maintenance of large walk-in cold room installation on a specific named site. The protocol and guidance shall be read in conjunction with PQS specification **E001/LWICR01.1**, to which it refers and which describes the requirements for a generic cold room installation, suitable for storing vaccine, assembled using prefabricated insulated panels and packaged split type cooling units.

Users should refer to PQS Type Examination protocol **E001/LWICR01.1-VP2.2**, **Section 3** – **Terms and definitions** for words or phrases highlighted in blue.

The document is designed to be completed by an employer working together with a QA assessor. It can be used to specify and commission equipment with a gross internal cubic capacity exceeding 40m³ (LWICR) assembled using prefabricated insulated panels and packaged split type cooling units. This equipment shall be installed in an existing building or a newly constructed building which is fully weatherproof.

Introduction

Unlike other cold chain equipment, large walk in cold rooms are purpose made and must be assembled and commissioned on site. This is a ten-step process for which the employer has overall organizational responsibility:

- **Step 1:** Appoint a QA assessor and other professional advisors as required.
- **Step 2:** *Establish the required vaccine storage capacity.*
- **Step 3:** *Choose the building where the equipment will be installed.*
- **Step 4:** *Define the equipment specifications.*
- **Step 5:** *Obtain tenders for the equipment.*
- **Step 6:** *Evaluate tenders and place order.*
- **Step 7:** Organize the building works needed to prepare the building for the installation.
- **Step 8:** Oversee the installation and commissioning of the equipment.
- **Step 9:** *Train the users and final handover.*
- **Step 10:** *Make arrangements for periodic planned preventive maintenance of the equipment.*

This document is designed to simplify the process and the following paragraphs below describe each step in more detail.

Step 1: Appoint the team

Technical and contractual expertise is required if the project is to proceed smoothly. The first step is to appoint a QA assessor who will oversee the specification writing, tendering, installation and commissioning process. It is essential that the QA assessor is entirely independent of the organization supplying and installing the equipment.

For smaller projects, a competent person from within the commissioning organization may be suitable. For larger projects the QA assessor should be a qualified engineer. If extensive building works are required, there may also be a need for an architect or other building professional.

Step 2: Calculate required capacity

Estimate the net volume of vaccine and other cold chain products to be stored, in litres or cubic metres. This step is critical – estimates must be as accurate as possible and must take into account existing and future needs, including new vaccine introduction, programme expansion and population growth. Once this figure has been calculated it can be used to establish the approximate dimensions (area and volume) of the cold store¹.

Step 3: Choose the building

Decide where the equipment is to be installed. This is another critically important step, which will have long-term implications for the efficiency of the vaccine supply chain. The building needs to be in the correct location to optimize the supply chain. It must be accessible to staff and delivery vehicles, large enough to accommodate the equipment, in good condition, have suitable finishes, have adequate ventilation, and must be supplied with the correct electricity rating, water supply, telephone and internet connections. In some cases a new building may have to be purchased or constructed to meet these requirements.

Step 4: Define the equipment specifications

Use the PQS Type Examination protocol **E001/LWICR01.1-VP2.2** to describe the chosen building and define the equipment specifications that you require. Do this by completing the data entry fields in **clause 5.1.3** and the data sheets in **Annex 1** – **PART 1: Site requirements schedule** and **Annex 1** – **PART 2: Installation checklist**. Complete all the data entry fields in the document. This information, together with the information from Step 2 is used to obtain tenders (Step 5). The legal manufacturer shall be responsible for preparing the final room designs. The employer shall be responsible for checking and approving these designs.

Step 5: Obtain tenders for the equipment

If equipment is procured through UNICEF Supply Division, UNICEF will procure using their current Long Term Arrangement (LTA). Otherwise:

- **Shortlist cold room suppliers:** Contact PQS prequalified cold /freezer room suppliers registered for the region in which your country is located and establish those able to provide the complete components of the cold/freezer room. Prepare a tender list of at least three companies.
- **Shortlist installers:** Contact qualified cold room installers in your country and establish which are able to provide the necessary installation service. Prepare a

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¹ The Immunization Supply Chain Sizing Tool is designed to help with both these tasks (available upon request to pqsinfo@who.int

- tender list of at least three companies.
- Shortlist maintenance contractors: Contact qualified cold room maintenance contractors in your country and establish which are able to provide the necessary long-term preventive and emergency maintenance services once the installation is completed. Prepare a tender list of at least three companies.
- Prepare tender documents: Use this document to prepare the detailed technical specification and QA inspection procedure for the installation. Note: You must complete clause 5.1.3 of this document and the Annex 1 and Annex 2 schedules before inviting tenders from cold room manufacturers and installers. The completed document, together with a copy of specification E001/LWICR 01.1, to which it refers, should be used to obtain tender offers for the installation components. If an event logger system conforming to specification E006/TR03 is required, a completed copy of the QA protocol E006/TR03-VP2.2 should also be prepared as part of the tender package.
- **Invite tenders:** Invite tenders in accordance with your organization's own internal procedures.
- Standby generator(s): Separately invite tenders for standby generator(s), if needed. Guidance on specifying and buying generators is given in **Section E001of** the PQS Catalogue.

Step 6: Evaluate tenders and place order(s)

Receive and evaluate tenders, agree an installation programme, and place an order with the winning supplier. The installation programme must allow time to prepare the building for the installation, and you must agree with the winning supplier what precise building preparation works are required.

Step 7: Organize the building works needed to prepare the building

Organize and oversee the building works needed to prepare the building for the installation in accordance with the supplier's requirements. Ensure that this process does not delay the installation programme. These works should always be specified and supervised by a competent building professional² under the direction of the OA assessor.

Step 8: Oversee the installation and commissioning of the equipment

The QA assessor should supervise the installation and oversee commissioning and user training. Use Section 6 of the Type Examination protocol E001/LWICR01.1-**VP2.2** and the **Annex 2 – Installation checklist** to monitor the installation contract. Use Annex 3 – Temperature mapping procedure to check the performance of the equipment.

Step 9: Train the users and final handover

Ensure that the users of the equipment and maintenance staff receive appropriate training as specified in clause 5.6, and that the installer provides all the handover

² If design work is required a structural engineer or an architect will be required. For small projects, the contractor may supervise.

information specified in clause 5.7.

Step 10: Make arrangements for planned preventive maintenance of the equipment:

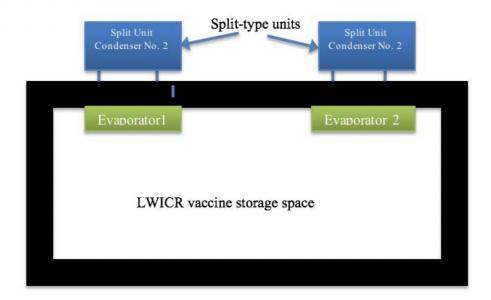
- Maintenance: Ensure that an effective planned and emergency
 maintenance system is in place and make sure that essential spare parts are
 available at all the times. Maintenance tasks may either be carried out by
 in-house maintenance technicians or be contracted out to a government
 agency or private sector provider.
- **Monitor:** Monitor the performance of the equipment in use and the planned maintenance intervals.
- **Renew:** If there is an external maintenance provider, ensure that the maintenance contract is renewed before it expires.

Large walk in cold room layouts (Split type)

Figure 1. General space layout for a large walk in cold room

A demonstration sketch shall be provided with split-type dual units. Note that, detailed drawings shall be provided at the time of placing the tender document. This shall be in tandem with the volume of the large walk in cold room in the tender bid.

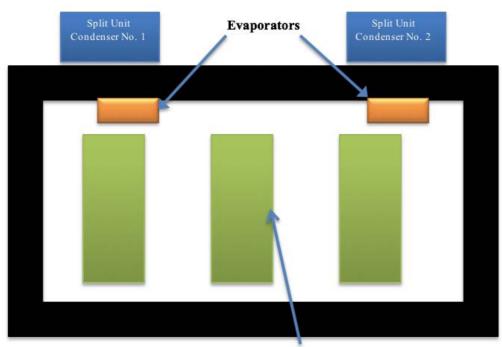
NOTE: The manufacturer/reseller shall provide a typical loading configuration of shelves for a large cold room exceeding 40 m²and in accordance with the proposal from the procuring agency. This shall be with split-type refrigeration units.



The following diagrams illustrate large walk in cold room layouts with different types of load storage system. Figure 2 shall be a sketch of a large cold room provided by the buyer with vaccine stored on shelves with maximized grossing factor of at least 50%. Figure 3 is similar, but space is allocated in the center of the room for a fixed pallet or pallets that can be used for the temporary storage of supplementary vaccines. Figure 4 is a pallet-standing store and Figure 5 is a high-rise pallet-racking store. The last two options depend upon the use of pallet handling equipment. Figure 6 shows a layout with a fully integrated temperature-controlled order assembly and packing area.

Figure 2: Large Walk-in Cold room shelving: Manual load handling.

The manufacturer shall provide a sketch of shelving including maximization of the middle space as per the bid request.



Mid space maximization shelves

Figure 3. Low rise pallet-standing store: mechanical load handling

NOTE: Refrigeration units not shown. Rooms wider than about six metres require mid-span support for the roof panels.

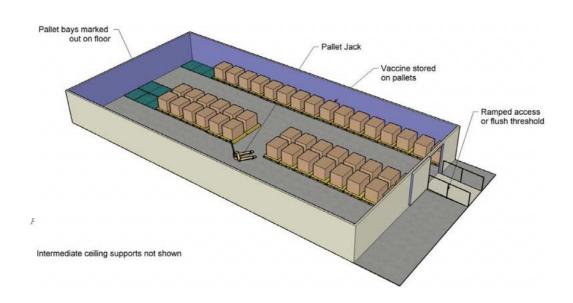


Figure 4. High rise pallet racking store: mechanical load handling

NOTE: Refrigeration units not shown. Rooms wider than about 6 metres require mid-span supports for the roof panels.

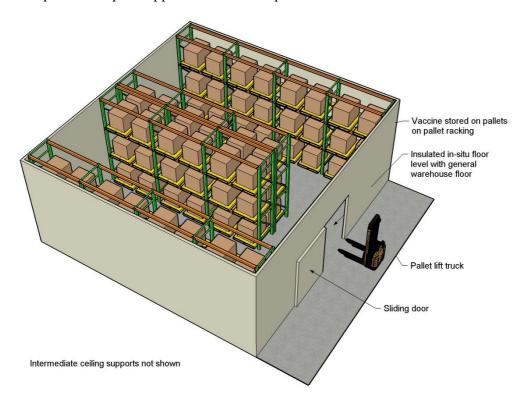


Figure 5. Large Walk in Cold room with attached temperature-controlled packing area

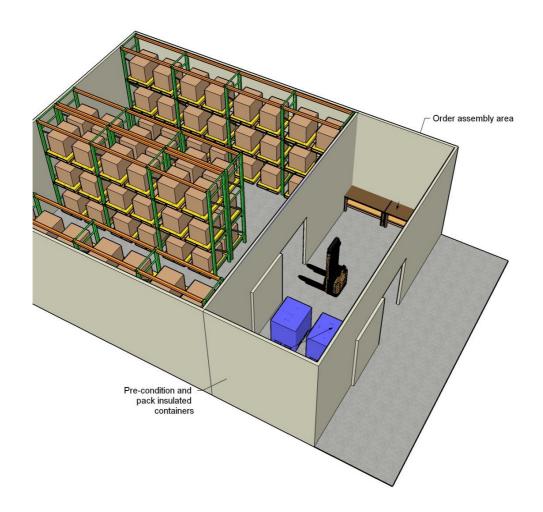


Figure 6. Table of dimensions for commonly used pallet types

Pallet standard/type	Length (metres)	Depth (metres)	Frontage clearance (metres)	Depth clearance (metres)
EUR 2 or 3:	1.20	1.00	0.10	0.05
EUR 6:	0.80	0.60	0.10	0.05
EUR pool:	1.20	0.80	0.10	0.05
ISO	1.07	1.07	0.10	0.05
ISO	1.10	1.10	0.10	0.05
ISO	1.14	1.14	0.10	0.05
ISO	1.22	1.02	0.10	0.05

Figure 7. Alternative pallet handling arrangements

