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Supplement 2

Design and procurement of storage facilities

Technical supplement to WHO Technical Report Series, No. 961, 2011

Annex 9: Model guidance for the storage and transport of time and temperature–sensitive pharmaceutical products

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Acknowledgments

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Contents

Abbreviations

BREEAM	Building Research Establishment Environmental Assessment Method
CCTC	Closed-circuit television
EEFO	Earliest-Expiry-First-Out
FIFO	First-In-First-Out
IFRC	International Federation of Red Cross and Red Crescent Societies
ISO	International Standards Organization
LEED	Leadership in Energy and Environmental Design
MSF	Médecins Sans Frontières
PPP	Public Private Partnership
SIA	Supplementary Immunization Activity
SKU	Stock-keeping unit
TTSPP	Time and Temperature-Sensitive Pharmaceutical Product
UPC	Universal Product Code
VEN	Vial, Essential, Nonessential

Glossary

ABC analysis: Tool for reviewing stock movement, which categorizes items by the volume and value of consumption during a specific period of time, usually one year. Class A items—10 to 20 percent of items, representing 75 to 80 percent of expenditures—are mostly high-volume, fast-moving medicines. Class B items are usually 10 to 20 percent of items, and 15 to 20 percent of expenditures. Class C items often represent 60 to 80 percent of the items but only about 5 to 10 percent of the total expenditures; these are the low-volume, slow-moving items. Thus, class C is a good place to look for items that might not be needed in stock at all times. See also *VEN analysis.*

Client: The organisation or individual that is responsible for procuring a building development; sometimes referred to as the *employer.*

Controlled or hazardous products: TTSPPs and other products with high illicit value: poisons, narcotics, psychotropic products, inflammable or explosive substances and radioactive materials.

Insulated shipper: A single-use insulated passive container, containing coolant, typically used to distribute TTSPPs by road or air transport.

Inventory turnover: A measure of the number of times inventory is sold or used in a time period such as a year. The equation for inventory turnover equals the cost of goods sold divided by the average inventory. Inventory turnover is also known as inventory turns, stockturn, stock turns, turns, and stock turnover.

Net storage capacity: The total volume available for storing TTSPPs, taking account of the type of load support system employed (floor-standing pallets, adjustable pallet racking, shelving units or cabinet). Net storage capacity is calculated by multiplying the gross storage capacity of the load support system by the utilization factor (less than one) that can be achieved for the chosen SKU type.

Pallet: Wooden or plastic platform designed to be lifted by pallet jack or forklift truck. Typically used for storing and handling tertiary cartons.

Passive systems: Systems which maintain a temperature-controlled environment inside an insulated enclosure, with or without thermostatic regulation, using a finite amount of pre-conditioned coolant in the form of chilled or frozen gel packs, phase change materials, dry ice or others.

Pharmaceutical product: Any product intended for human use or veterinary product intended for administration to food producing animals, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines. Medical devices are not included[1].

Primary container: Bag, blister pack, strip, bottle, cartridge, vial, ampoule, prefilled device, plastic dispenser, tube, single dose container or the like containing tablet(s), capsule(s), liquid preparation or the like.

[1] Definition from WHO/QAS/08.252 Rev 1 Sept 2009. *Proposal for revision of WHO good distribution practices for pharmaceutical products – Draft for comments*.

Refrigeration equipment: The term 'refrigeration' or 'refrigeration equipment' means any equipment whose purpose is to lower air and product temperatures and/or to control relative humidity.

Secondary pack or carton or market package: The package presentation intended for the end user (e.g. bottle + cap liner + dose cap + leaflets + carton) but not including packaging used solely for transport purposes (e.g. *Tertiary carton* or *Insulated shipper*). The secondary pack may contain multiple units of product.

Staging area: Zone(s) of a warehouse designated for the short term storage of incoming goods waiting to be moved into long-term storage, and also for storing outgoing goods awaiting shipment.

Standard Operating Procedure (SOP): A set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Standard operating policies and procedures can be effective catalysts to drive performance improvement and improve organizational results.

Stock-keeping unit (SKU): In the field of inventory management, a code number, typically used as a machine-readable bar code, assigned to a single item of inventory. As part of a system for inventory control, the SKU represents the smallest unit of a product that can be sold from inventory, purchased, or added to inventory. Applied to wholesale, retail, or production operations, the SKU can assist in monitoring transactions, tracking customer spending patterns, controlling inventory and purchasing, and providing information about pricing[2], for example via its Universal Product Code (UPC). In the context of this Technical Supplement, and depending on the level in the supply chain, an SKU may be a complete pallet, a tertiary carton, a secondary carton or a primary container.

Temperature-controlled: Includes any environment in which the temperature is actively or passively controlled at a level different from that of the surrounding environment within precise predefined limits.

Temperature-modified: Includes any environment in which the temperature is predictably maintained at a level different from that of the surrounding environment, but is not actively or passively controlled within precise predefined limits.

Tertiary pack or carton: The pack/carton that contains a number of secondary cartons; usually constructed of corrugated fibreboard. *Note:* the tertiary carton is not the same as the insulated shipper used for international air shipment of TTSPPs, although the insulated shipper may contain one or more of these cartons.

Time and temperature sensitive pharmaceutical product (TTSPP): Any pharmaceutical good or product which, when not stored or transported within pre-defined environmental conditions and/or within pre-defined time limits, is degraded to the extent that it no longer performs as originally intended.

Utilization factor: The percentage of the total volume available for storing TTSPPs that can reliably be achieved in practice, taking account of the types of stock-keeping unit

[2] Source: http://www.britannica.com/EBchecked/topic/1242199/SKU

(SKU), the types of load support system and the stock management systems used in the store.

VEN analysis: Method for categorizing stock as vital (V), essential (E), or nonessential (N). This system is sometimes modified to two categories—V and N. VEN analysis is often used to prioritize procurement when not enough funds exist to purchase all items requested. The system can also help determine which items should be kept in stock and which can be ordered when needed. See also *ABC analysis.*

1. Introduction

This technical supplement has been written to amplify the recommendations given in Sections 2 to 5 of WHO Technical Report Series No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products*[3]. Related topics are covered in the following Technical Supplements:

- *Estimating the capacity of storage facilities.*
- *Maintenance of refrigeration equipment.*
- *Maintenance of storage facilities.*
- *Qualification of temperature-controlled storage areas.*
- *Security and fire protection in storage facilities.*
- *Selecting sites for storage facilities.*
- *Temperature-controlled transport operations.*
- *Temperature and humidity monitoring systems for fixed storage areas.*
- *Temperature mapping of storage areas.*

1.1 Requirements

Pharmaceutical warehouses need to be efficiently laid out and should contain all the necessary storage areas, goods assembly, packing, receiving and dispatch bays and office and ancillary accommodation needed for the effective operation of the store. Pharmacies and health facilities should be laid out so as to minimize dispensing errors and should provide a safe and comfortable environment for staff and patients. Facilities of all sizes and types must be able to store and protect TTSPPs and other products against damage and degradation during storage.

1.2 Objectives

This document provides general advice on the process of designing, procuring and commissioning pharmaceutical warehouse buildings which are intended to store pharmaceutical products, predominantly under temperature-controlled conditions. It also touches on issues relating to the design of smaller scale facilities, such as pharmacies. It covers the following topics:

- The main design requirements for a pharmaceutical warehouse or dispensing facility.
- Preparing and agreeing a design brief.
- Appointing and working with a design team.
- Choosing a procurement route.
- The client's role in tendering.
- The client's role during the construction stage.

[3] http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf

- Commissioning and handover.

The overall objective is to help the reader to act as an informed client. The supplement contains general guidance material only. It assumes that a professional design team will be commissioned to work with the client to determine the required capacity of the facility, develop a detailed site-specific building brief, prepare outline drawings for client approval, prepare construction and tender documentation, and be responsible for overseeing the construction and commissioning process. Alternatively, most of these essential tasks may be carried out as part of a turnkey offer from a suitably qualified construction company.

Although it provides links to some useful on-line resources, the supplement is not intended to be a detailed design guide. Readers are advised to consult the reference documents in order to obtain a fuller understanding of this extensive subject.

Note: Before any storage facility can be designed, it is essential to identify and quantify the products to be stored in the facility and to establish the specific environmental and security conditions under which each of these products must be kept. Readers should refer to the companion supplement: *Estimating the capacity of storage facilities.*

1.3 Target readership

This supplement will be of use to senior personel responsible for procuring public sector medical warehouses and other related facilities. Such a person will generally be responsible for the entire procurement process, will act as the client and will be responsible for preparing the building brief, appointing and managing the design team and overseeing the construction and commissioning process.

2. Guidance

Well designed, correctly sized, suitably located and well managed pharmaceutical stores, pharmacies and other facilities, combined with an efficient distribution system, can significantly improve the operational efficiency of a health service by ensuring that patients receive the correct medicines in good condition and in a timely fashion.

2.1 Associated materials and equipment

None required.

2.2 Design of pharmaceutical warehouses

Comprehensive guidance on the design, layout and operation of medical warehouses is given in the on-line document, *Guidelines for Warehousing Health Commodities,* published by JSI | DELIVER. The guideline includes an overview of warehouse planning and covers the various types of load support system, including shelving, pallet racking, gravity flow systems and carousels, the selection and the use of materials handling equipment such as pallet jacks and forklift trucks. It also provides guidance on human resource planning, warehouse management systems and the use of bar coding technology. Another very comprehensive reference, which includes case studies, is the on-line guide from Link51: *Racking & Warehouse Storage Guide*. Other useful sources of design advice are given in the **References** section.

This section starts with a general overview of warehouse layout planning and then concentrates on design issues that relate specifically to temperature-controlled storage. These topics are not specifically covered in the JSI guideline.

2.2.1 Low-carbon design and environmental auditing

A recognized and appropriate environmental audit system, such as BREEAM, LEED or Pearl, should be adopted at the beginning of the design stage. All three audit schemes can be used to guide and evaluate the design and to assess the subsequent operational performance of the completed building[4].

Temperature-controlled warehouses are potentially energy intensive because they incorporate energy-hungry refrigeration and ventilation systems. However, careful design can greatly reduce energy consumption and it is possible to design these buildings so that they are *net-zero energy*; in other words, they generate as much energy as they consume from an ambient energy source such as passive heating and cooling, roof-mounted photovoltaic panels or other renewable energy sources. Useful guidance material has been published which describes the various measures that can be taken to minimize warehouse energy consumption in a range of climate zones[5,6]. In addition, careful choice of locally

[4] BREEAM and LEED and Pearl audits are internationally recognized. The Pearl rating system has been developed by the Abu Dhabi Urban Planning Council to suit the needs of desert climates. The three systems have different emphasis – for example the Pearl system has a particular focus on water conservation.
[5] ASHRAE. *Advanced Energy Design Guide for Small Warehouses and Self-Storage Buildings.*
[6] Target Zero. *Guidance on the design and construction of sustainable, low carbon warehouse buildings.*

available construction materials can further reduce the whole-life environmental impact of the project.

2.2.2 Warehouse layouts

Warehouse layout is dictated by the type of warehousing operation and the need to achieve an efficient flow of goods into and out of the building; it is also constrained by the physical layout of the site and available road access points. In addition, it is affected by the need to allow for future expansion. Remember too that the internal layout is certain to be changed over the life of the building, both to accommodate new product lines and to implement new warehouse technologies. Designing the building for long-term flexibility is therefore critically important.

Type of operation

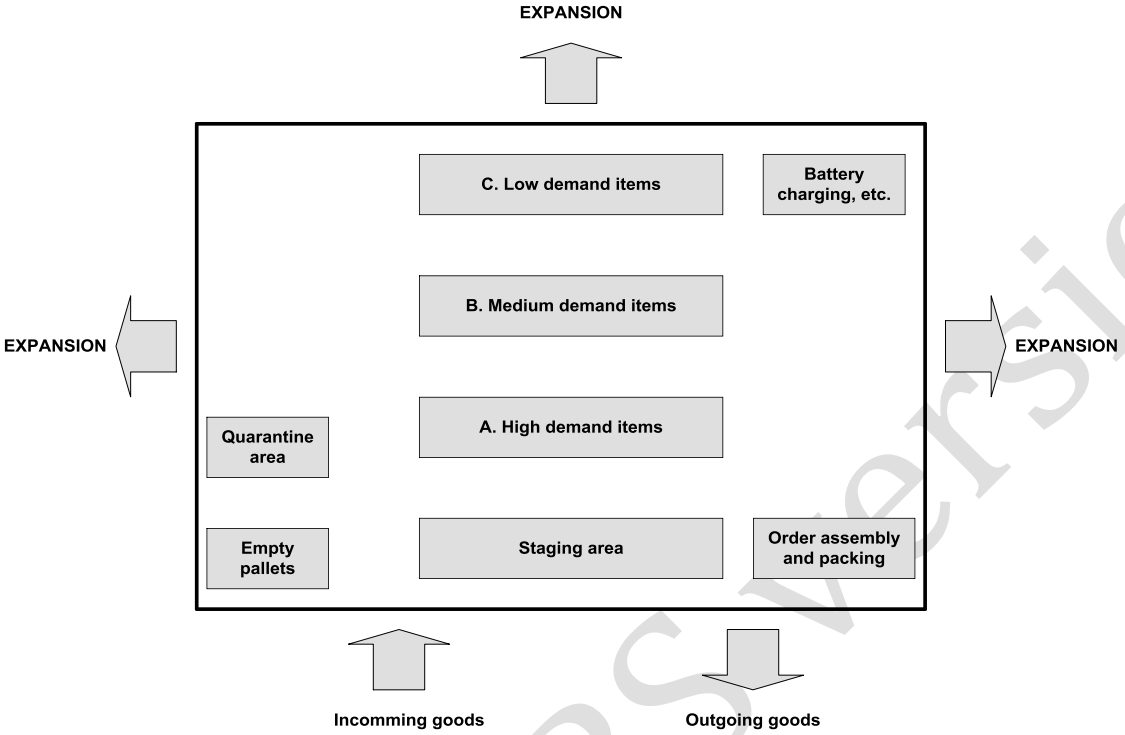
The focus of this supplement is the *transhipment warehouse*, a type that receives products in bulk from multiple suppliers, stores them for a period of time and then breaks them down into suitably sized stock-keeping units (SKUs) for onward delivery to lower level stores or health facilities. Depending upon, the extent of bulk breaking at the higher level – say from a pallet SKU to a tertiary carton SKU – lower level stores may also have a break-bulk function; for example from the tertiary carton down to the secondary carton.

An alternative delivery approach, which largely eliminates the lower level storage function, is the *cross-dock centre.* This serves as a local hub for a radial distribution arrangement. Products are received in bulk from a transhipment centre, but with individual packages already labelled and sorted by end destination – for example a pharmacy or health facility. The packages are not put away into stock but are sent out on local delivery vehicles. Items remain in the warehouse for the shortest time possible, with same-day despatch as the target.

Layout options

There are two main layout options – the *'U' flow* the *'Through' flow*. Figure 1 shows the 'U' flow arrangement.

Figure 1 – 'U' flow warehouse



Adapted from Richards, 2011.

Goods receipt and dispatch are located on the same side of the building and products are taken into stock in accordance with their ABC designation, with the highest demand items nearest the loading bays.

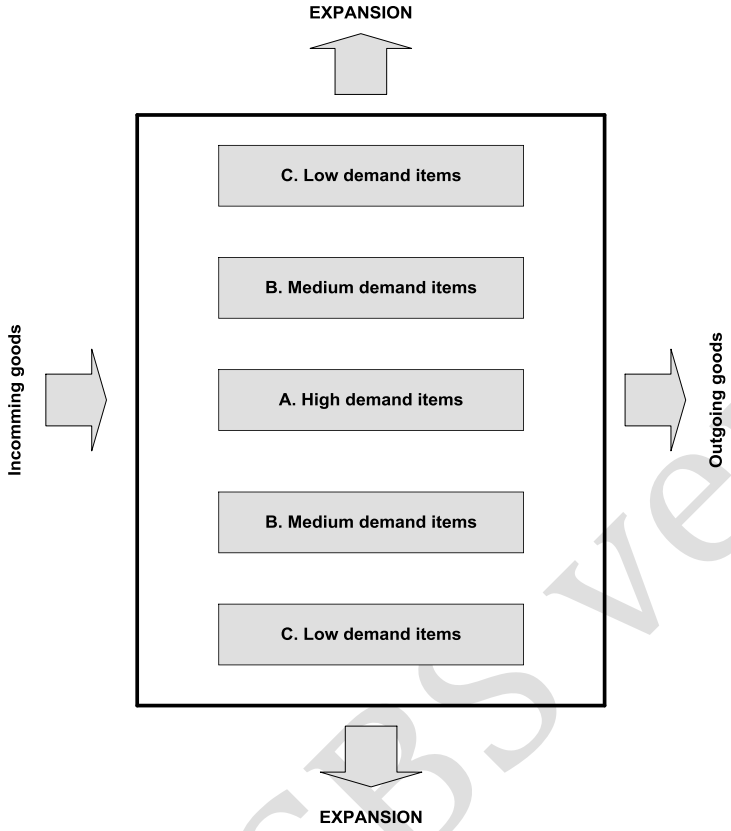
Advantages of 'U' flow:

- Good utilization of dock resources because the receiving and shipping processes can share dock doors.
- Facilitates cross-docking because the receiving and despatch areas are next to one another and can operate together.
- Excellent lift truck utilization because put away and retrieval trips are easily combined and storage locations closest to the receiving and dispatch docks are natural locations to house fast moving 'A'-rated items.
- Provides excellent security because only one side of the building is used for entry and exit.
- Allows scope for expansion in three directions.

A disadvantage of the 'U' flow arrangement is that congestion can occur if there is heavy incoming and outgoing traffic at the same time.

Figure 2 shows the 'Through' flow arrangement.

Figure 2 – 'Through' flow warehouse



Adapted from Richards, 2011.

Goods receipt and dispatch are located on opposite sides of the building. High demand items are stored along the central axis. The advantage of this arrangement is that there is little risk of congestion at the loading docks. However, security is an increased problem because of the two-sided arrangement. This is likely to require two security gates with access roads on both sides of the building. In addition, the potential for expansion is limited to two directions only.

Temperature zones

The size and layout of the temperature zones within the warehouse will be determined by the labelled storage temperatures of the products to be stored, the volume of goods in each of these categories and the SKU for each product type. See Technical Supplement: *Estimating the capacity of storage facilities.* In addition, ABC or VEN analysis will determine how accessible the product needs to be, and how it will be picked during order assembly. See: JSI | DELIVER: *Guidelines for Warehousing Health Commodities.*

2.2.3 Temperature-controlled storage areas

In this context, a temperature-controlled storage area is a zone in which the temperature is consistently maintained within a pre-defined temperature range, but above that required for refrigerated or frozen storage; a typical range is +15°C to +25°C. In this type of store, temperature is most efficiently controlled by a balanced combination of active and passive techniques. Depending on the climate, these are likely to include:

- An external building envelope with a high standard of thermal insulation.
- Tight control of air infiltration through the external envelope.
- Control of heat loss and heat gain through door openings; this can be achieved using lobbies and strip curtains.
- Passive or low-energy heating and cooling systems such as ground-source heat pumps, night-time cooling[7] or evaporative cooling.
- Control of temperature stratification using a purpose designed de-stratification system that maintains even temperature distribution throughout the volume of the temperature-controlled zone[8].

Uncontrolled temperature stratification is a major problem in a pharmaceutical warehouse. Even in temperate climates, summer temperatures in excess of 35°C can occur in high-bay warehouses if de-stratification measures are not taken; temperatures as high as this expose pharmaceuticals and medical devices to the risk of heat damage.

In some settings, relative humidity will also need to be actively controlled, especially in humid climates where the dew point may well lie within the controlled temperature range[9]. Under these circumstances, high humidity and condensation may affect the stored product[10].

2.2.4 Cold rooms and freezer rooms

The design requirements for cold rooms and freezer rooms are similar to those described for temperature-controlled stores. Products labelled for storage in the sub-zero and +2.0°C to +8.0°C ranges represent a small percentage of all pharmaceuticals. Consequently, in a warehouse storing general pharmaceuticals, cold rooms and freezer rooms will only occupy part of the building.

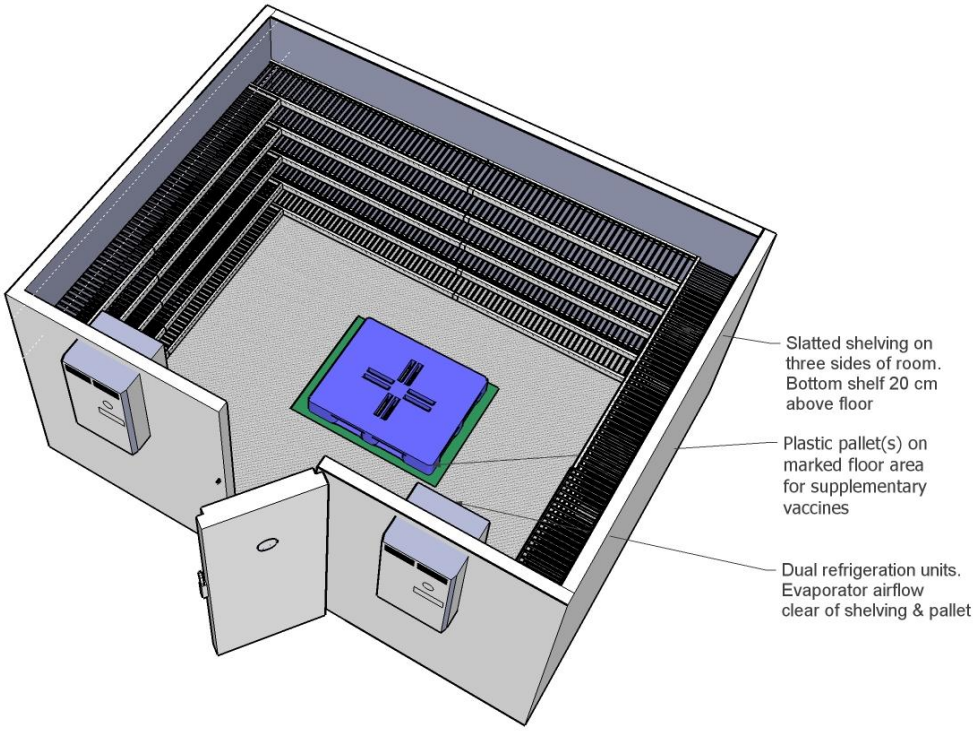
Typically cold rooms and freezer rooms will be constructed within the main building envelope, using pre-fabricated insulated panels. All rooms should have 100% standby capacity in the event of a refrigeration unit failure. It is important for maintenance and inspection purposes to locate the room enclosure so that both wall panels and roof panels can be accessed – see companion Technical Supplement: *Maintenance of refrigeration equipment.*

Depending on the product volumes involved and the available ceiling height in the warehouse building, there are three approaches to laying out the rooms:

Walk-in rooms with shelving: For smaller rooms up to 100 m^3 or so the simplest arrangement is to build walk-in rooms with adjustable shelving as the load support system. Figure 3 illustrates a typical arrangement. This particular arrangement includes an area in the centre of the room for the temporary storage of campaign vaccines and other overspill products.

[7] Night-time cooling uses cool air purging to replace air that has warmed up during the day. Alternatively, cool air can be circulated through structural voids to cool the structure itself.
[8] See for example: *Pharmaceutical Warehouse Temperature Control* http://jetenvironmental.com/pharmacetical-warehouse-temperature-control
[9] In one West African country, the dew point can be as high as +23°C.
[10] See: FDA. *Guidance for Industry Q1A(R2) Stability testing of New Drug Substances and Products.*

Figure 3 – Walk-in cold room



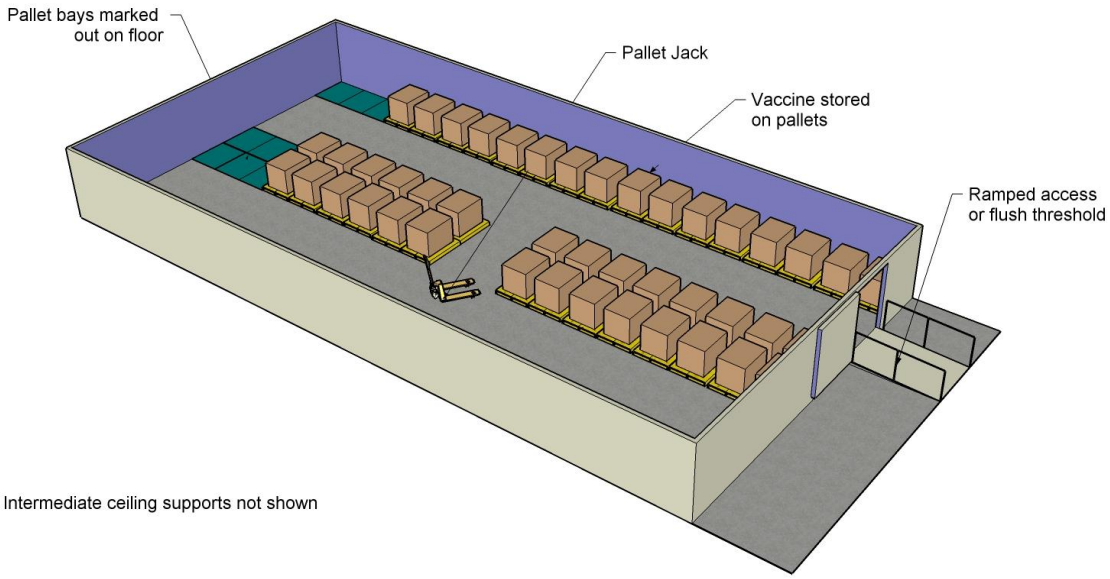
The diagram shows dual 'monobloc' refrigeration units. Monobloc units are easy to install but discharge waste heat from the condenser into the general warehouse space. Particularly in hot climates, a better arrangement is to have a 'split' system with the condenser unit located outside the building.

Walk-in units generally have a floor constructed of insulated panels. These are strong enough to take foot traffic or light trolleys but they are not suitable for heavy mechanical handling equipment. In the case of a freezer room, it is generally necessary to install a heater mat below or within the floor panels. This prevents sub-zero temperatures propagating through the main floor of the building and freezing the sub-soil. Over time, sub-soil freezing will cause frost-heave and can crack a concrete slab.

Pallet standing: This arrangement can be used for larger cold rooms where product is stored on pallets and there is insufficient height to install pallet racking. Figure 4 shows a typical layout. Here, the pallets are moved using manual pallet jacks or electric low-lift trucks. The refrigeration units should be split systems, arranged so as to ensure a constant even temperature distribution throughout the room. The insulated floor in a pallet-standing store needs to have sufficient load capacity to support the specified mechanical handling equipment. Typically this will be concrete, with an insulation layer below the slab. The floor should be clearly marked to show permitted pallet positions. These positions should take account of the type of mechanical handling equipment used in the store, the need to ensure even air distribution and any restrictions on location determined during temperature mapping of the room[11].

[11] See companion technical supplement: Tem*perature mapping of storage areas.*

Figure 4– Pallet standing store

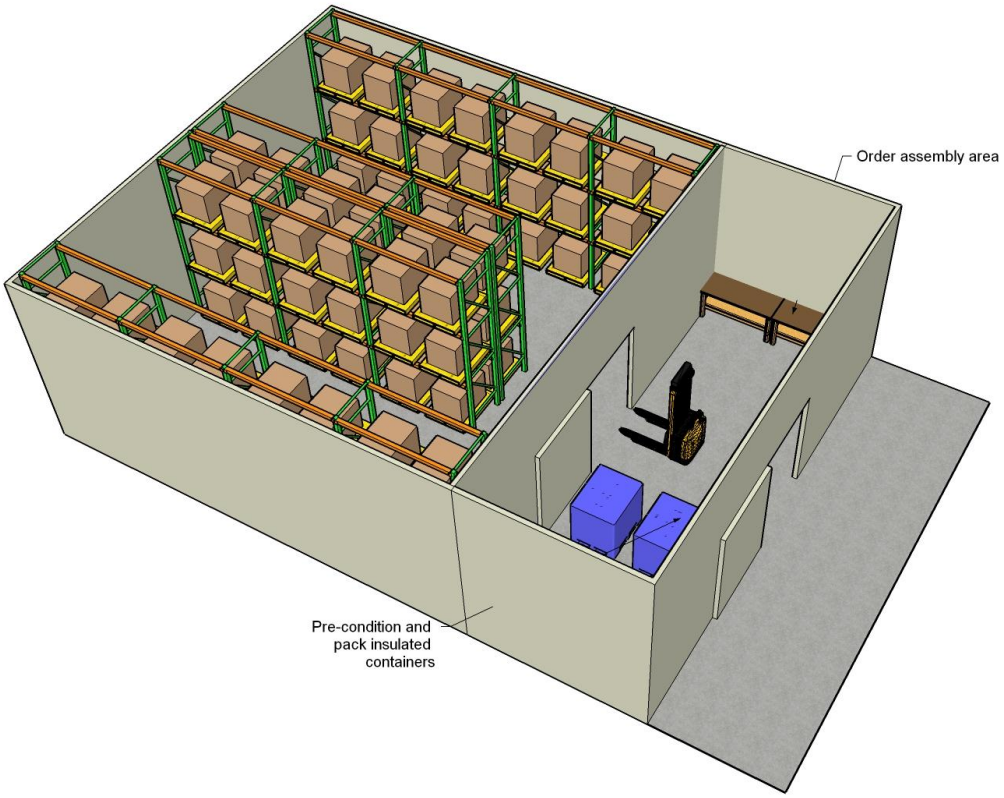


Pallet racking: If sufficient height is available to install pallet racking, a high rise cold room is likely to be the most space and volume-efficient arrangement for a larger pallet store. Figure 5 shows a typical arrangement, in this case with a temperature-controlled packing area immediately adjacent to the store. As with temperature-controlled stores, it is important to avoid temperature stratification and to ensure that the air circulation system maintains an even temperature throughout the space. The racking arrangement should take account of the type of mechanical handling equipment used in the store, the need to ensure even air distribution and any restrictions on location determined during temperature mapping of the room[12].

The refrigeration units and floor construction are similar to those described for a pallet standing store. Load handling will require a counterbalanced electric lift truck. Depending on the size of the room and the planned level of stock movement, this may be pedestrian-controlled, or a stand-on or sit-on model.

[12] See companion technical supplement: *Temperature mapping of storage areas.*

Figure 5 – Pallet racking cold room with temperature-controlled packing area



2.2.5 Order assembly and packing area

All products should be packed at or close to their labelled temperature. Depending on the type of products being handled and the way they are packed, the order assembly and packing area may be separated from the staging area, or be part of it. If the majority of products are kept in the temperature-controlled zone, it may be necessary to have a separate order assembly and packing area for TTSPPs labelled at +2.0°C to +8.0°C or below. One possible option is to do this in an area immediately adjacent to the cold room where the product is stored – see Figure 5 above.

If passive containers are used for these products, the packed containers may then be moved to the general staging area, although this may reduce the cold life of the container if the holding period is very long.

If refrigerated trucks are used and TTSPPs are packed in uninsulated containers, the holding area must be contiguous with the loading dock and kept at, or close to, the labelled temperature of the product until the truck is loaded.

2.2.6 Staging area

The staging area is situated next to the loading dock. It is the zone where incoming and outgoing goods are held for despatch or temporarily stored in preparation for putting away into stock, or for moving returned or counterfeit products into quarantine. The temperature of the staging area should reflect the type of goods held and the way in which these goods are packed.

If TTSPPs are being shipped in passive systems it is prudent to control the temperature in the staging area; this limits the exposure of the package to excessively high or low temperatures and extends its cold life whilst it is waiting to be transferred to storage, or to be loaded onto a vehicle. See Technical Supplement: *Temperature-controlled transport operations.*

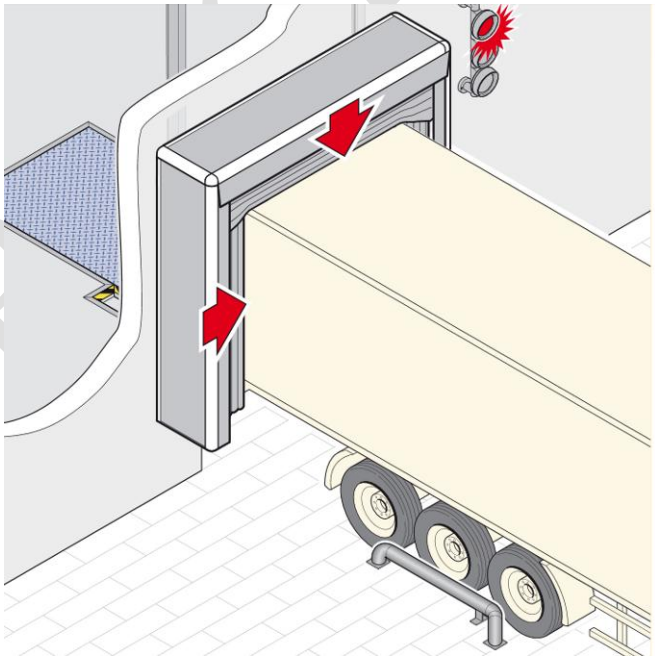
If TTSPPs are being shipped, in uninsulated packages, by refrigerated vehicle, the staging area must be fully within the temperature-controlled zone. This is essential in order to minimize exposure of the product to temperatures above or below their labelled storage range whilst awaiting transfer.

2.2.7 Loading docks

The loading dock floor may be at ground level, it may be raised to the height of a standard delivery vehicle, or there may be a height adjustable mechanism to accommodate vehicles of different sizes. The choice will depend on the size of the operation and the types of vehicle entering and leaving the site.

In order to minimize heat loss or heat gain through the dock area, vehicles should preferably be coupled to the building by a dock seal; it must also be possible to close off the opening when no vehicle is in place. This arrangement is essential where vehicles are coupled to a temperature-controlled loading bay/ holding area. Figure 6 shows an example of an insulated, inflatable dock seal suitable for this application. Extended dock seals are also available, incorporating a dock levelling platform.

Figure 6 – Dock seal



Source: http://www.hormann.co.uk

If there is a mixture of large and small vehicles – for example refrigerated trucks delivering bulk products on pallets to the receiving bay and out-going delivery vans collecting small consignment of picked products at the despatch bay – it is likely that a combination of raised and level docks will be needed.

2.2.8 Other areas

There needs to be a designated and locked area for holding counterfeit and returned products. There may also be a requirement for a sampling area and secure zones for keeping dangerous goods and controlled drugs, some of which may be TTSPPs. If explosive substances are stored, these should be in a separate explosion-proof area fitted with an explosion hatch. The hatch should be arranged so that there is no risk to staff or passers-by in the event of an accident.

2.2.9 Temperature monitoring, mapping and qualification

All freezer rooms, cold rooms and temperature-controlled storage, packing and staging areas must be equipped with continuous temperature and/or humidity monitoring equipment as described in the companion supplement: *Temperature and humidity monitoring systems for fixed storage areas.*

In addition, all these areas should be qualified and temperature-mapped – see companion supplements: *Qualification of temperature-controlled storage areas* and *Temperature mapping of storage areas.* Initial mapping should be carried out in both the hot and cold seasons. Mapping should be repeated at regular intervals and after any significant modification to the building, the stock layout, or the heating or cooling system.

2.3 Design of dispensing facilities

Dispensing facilities range in size from large hospital and private sector pharmacies down to small-scale rural health facilities. In many of these facility types, the area devoted to storage will occupy a small part of the building footprint – in the smallest facilities it may simply be a medicine cupboard and a refrigerator. However small the facility, due regard should be given to the basic principles of temperature and humidity control and the physical security of the products being stored – effectively the same requirements that apply in a pharmaceutical warehouse.

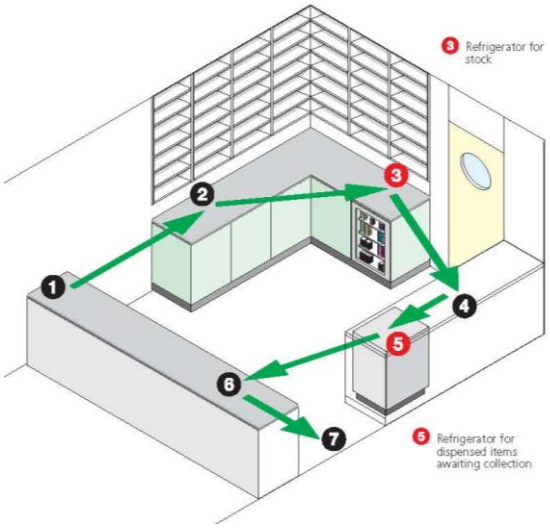
As well as storing pharmaceuticals and related supplies, dispensing facility operations also involve direct or indirect contact with the patient. There are three main types of contact: issue of medicine for self-administration at home; issue for supervised consumption at the dispensing point, or issue for use during a medical intervention by a health worker.

In addition to the risks associated with incorrect storage practices, which are common to all storage operations, there is the added risk of dispensing error, or errors arising from miscommunication with the patient or health worker. These risks can be mitigated by good ergonomic design, effective organization of stored products, and efficient workflow. A comprehensive on-line design guide, published by the UK National Health Service, addresses these issues[13]. Figure 7 illustrates the layout of the working area and one arrangement for the dispensing area.

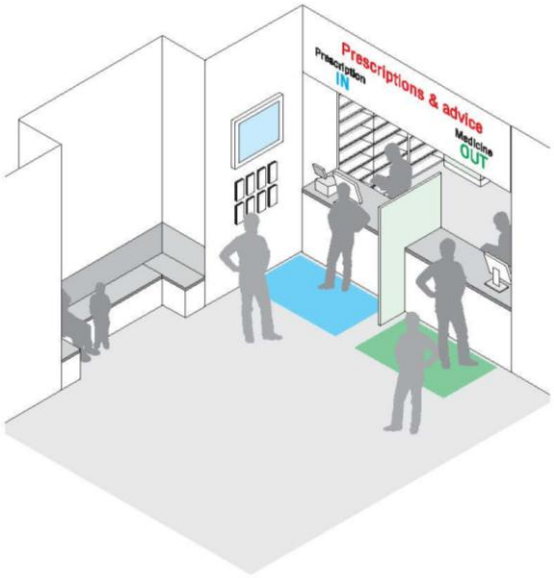
[13] See: NHS National Patient Safety Agency. *Design for patient safety: A guide to the design of the dispensing environment*.

Figure 7 – Pharmacy layout

Workflow in working area



Dispensing and waiting area



Source: *A guide to the design of the dispensing environment*

The following sub-sections highlight some of its key recommendations; specifically those that relate to the physical layout of a dispensing pharmacy:

2.3.1 Workflow

Effective workflow planning is as critical in the dispensing environment as it is in a warehouse. Dispensing is a multi-stage process and it is important to identify and understand the importance of each step. Poorly-planned workflow can result in confusion, fatigue and increased risk of error.

- The pharmacy layout should promote efficient workflow; this positively affects dispensing activity, allowing pharmacists more time for patient counselling.
- Break the workflow process down into its constituent parts, look at each individual stage, and take steps to make each stage as safe as possible.

2.3.2 Working environment and ergonomics

A good working environment promotes safe working and reduces stress levels for both staff and patients.

- Provide good quality lighting, especially over dispensing benches and near computer screens. Evidence shows that high levels of illumination with daylight-type luminaires significantly lowers dispensing errors..
- Keep the working environment at a comfortable temperature, below +25°C, and at a comfortable humidity level.
- Ensure that work surfaces, shelving and computer workstations are designed to minimize fatigue.

- Use grey or cream coloured finishes on dispensing benches. White surfaces provide an unsuitable background for viewing white packaging and medication.
- Minimize background noise by screening and other design approaches.
- Provide appropriate measures at the dispensing point so that both staff and patients feel secure.
- Cushioned flooring alleviates tiredness and helps staff stay alert.

2.3.3 Incoming stock

If newly delivered stock is mixed with current stock before it is checked off, there is a risk that it will be put away in the wrong storage area.

- Assign a temporary storage area for delivered stock before it is put away.
- Have a dedicated bench section for unpacking and checking off.
- Ensure that TTSPPs can be unpacked, checked off and immediately put away into the designated refrigerator.

2.3.4 Refrigerators

Cluttered and overstocked refrigerators make it difficult to select the correct medicine. If stock and completed prescriptions are kept in the same refrigerator, the two may get mixed up.

- Have one refrigerator for stock and another for completed prescriptions, with the latter located near the prescription collection point. If a single refrigerator has to be used, find an effective way of separating dispensed medicines from stock so that they cannot be confused with one another.
- Arrange the stock so that it is well spaced and easily seen.
- Use refrigerators that are suitable for the operating environment[14]. Glass-fronted pharmacy refrigerators allow stock to be checked without opening the door. However, this type of equipment is not suitable in places with unreliable electricity because their holdover time during a power cut is too short.
- Provide refrigerators with continuous temperature monitoring devices and check and record temperatures twice daily[15].

2.3.5 Controlled drugs

Cluttered and overstocked drugs cupboards make it difficult to select the correct medicine.

- Provide a controlled drugs cupboard large enough to meet the dispensary's needs.
- Arrange the stock so that it is well spaced and easily seen.

2.3.6 Waste and returns

Returned or expired medicines may be confused with medicine stock if it is stored in the same area of the dispensary.

[14] See *WHO PQS catalogue*, Section E004.
[15] See *WHO PQS catalogue*, Section E006.

- Returned or expired stock should be stored in a separate section of the dispensary to differentiate it clearly from medicine stock.
- If possible, keep waste and returns in a separate room away from the main stock, or in clearly designated cupboards, or under bench areas.
- Sharps bins, etc. should also have a designated area for storage and should be separated from stock.

2.3.7 Location and arrangement of stock

For operational efficiency, and to avoid dispensing errors, it is essential to be able to find medicines easily.

- As far as possible, use a simple alphabetical A–Z stock storage system organized by proprietary or generic name as appropriate.
- TTSPPs and controlled drugs should be similarly arranged.

2.3.8 Separation of stock

Stock that is unseparated and muddled can increase the risk of selection errors.

- The use of shelf dividers helps ensure that different products, strengths and formulations do not become mixed and confused.
- The use of sloping pull-out drawers that enable stock to be seen and easily retrieved may also help reduce selection errors.

2.3.9 Patient areas

Disorderly queuing can cause confusion and distract both patients and staff. Confidentiality is essential when pharmacists talk to patients about their medicines. Waiting patients should be kept away from the counter so that they cannot overhear these discussions.

- Use effective signage so that patients know where to go to hand in or collect prescriptions, or to ask for advice. This leads to shorter queues, less confusion and improved communication. It also reduces pressure on pharmacy staff and allows them to concentrate without interruption.
- Use techniques such as different coloured flooring and counter dividers, to demarcate areas where confidential discussion takes place.
- Locate patient waiting areas away from areas where consultations take place. Provide adequate seating for the elderly and disabled.

2.3.10 Supervised consumption

Some medicines – for example TB antibiotics, or drugs given to substance misusers – should be self-administered by the patient in the pharmacy environment in order to confirm that they have been taken, or to prevent misuse or sale on the black market. In such cases there is an enhanced issue of patient privacy and staff security.

- Ideally, provide a separate area for supervised consumption and other activities associated with substance misusers e.g. needle exchange.

- Consider the provision of security measures to protect staff, such as panic buttons and CCTV.
- Consider higher counters in these areas; this enhances security without compromising communication between staff and patients.
- Ensure sharps bins, etc. are inaccessible to other patients.

2.4 Building procurement

The chosen procurement route for a building project should fit the client's long-term objectives; these include speed, cost and quality of construction, risk mitigation, asset ownership, financing, and specific project constraints. In order to choose the most appropriate procurement route, the client may need to obtain independent advice[16].

2.4.1 Preparing and agreeing the brief

It is important that the client understands enough about warehouse design and operations to be able to communicate the initial requirements to the team at the time of appointment, in the form of a *strategic brief*. This document describes the requirements for which the building design provides the solution; it is crucial to the success of the project. The brief evolves over the life of the project and requires specialist input from the consultant team,

The stages in brief development are described in **Annex 1.**

2.4.2 Appointing and working with the consultant team

Good buildings are built when a knowledgeable client is matched with a team of expert consultants, all parties communicate effectively and timely decisions are taken which meet pre-defined project milestones. It is the client's responsibility to select and appoint the right consultants for the job – on a large lump sum project this will include an architect, structural engineer, services engineer, and probably a cost consultant. The consultant team for other procurement routes may be smaller, depending on the contractual arrangement with the design and build or Public Private Partnership (PPP) contractor. For a warehouse project of significant size, the consultant team must include members with expertise in this specialist field. At this stage it is also good practice to appoint the commissioning team whose responsibility is to bring the building into operation immediately after handover; ideally this team should also be involved in the design process, including the design risk assessment.

2.4.3 Design risk assessment

The design process should include a fully documented *design risk assessment* exercise. This exercise should identify risks and eliminate them wherever possible; where elimination is not possible, residual risks should be reduced and managed[17].

Both the construction and operation of warehouses and pharmacies exposes workers to health and safety risks. Day-to-day operational risk mitigation is one of the key

[16] This section has been developed, with permission, from guidance material at: http://www.designingbuildings.co.uk/

[17] http://www.designingbuildings.co.uk/wiki/Risk_assessment describes UK risk assessment practice.

responsibilities of the building management team. However decisions made by the design team may also have long-term consequences for safe operation and maintenance of the building and will certainly affect the safety of workers during the construction phase. For example, all construction activities and many post-construction maintenance operations require working at height, with the consequent risk of injury from falls and from falling objects. It is the responsibility of the design team to consider both how design decisions can reduce the need for these activities and to provide adequate protection for workers when these tasks cannot be avoided. Careful consideration of design risk issues throughout the design process is likely to lead to a building that is both easier to construct and safer and cheaper to operate.

2.4.4 Choosing a procurement route for new buildings

The client and consultant team must agree the appropriate procurement route at an early stage. **Annex 2** describes three major types of building contract; there are numerous variants on each of these alternatives:

- *Lump sum:* This is the traditional procurement route. The client is responsible for developing the design brief and their appointed design team is responsible for the building design; the contractor then builds this design for an agreed sum;
- *Design and build:* The client remains responsible for the design brief; some or all of the design responsibility is passed to the contractor;
- *Design, build, finance and operate:* This route is typified by a Public Private Partnership (PPP) arrangement; the client defines a design brief or a service level requirement; all responsibility for facility design, construction and day-to-day operation is shifted to the contracted party.

Each route has its advantages and disadvantages. In all cases, effective contract management requires the client and their advisers to have good knowledge of the relevant contractual procedures and a clear understanding of the responsibilities and duties of the parties to the contract.

2.4.5 Choosing a procurement route for building alterations or refurbishment

For projects involving the refurbishment or alteration of an existing building, both the lump sum and design and build routes can be followed. The PPP approach might also be suitable, provided the PPP provider has access to a suitable warehouse property portfolio.

2.4.6 The client's role in tendering

A tender is an offer for the supply of goods or services made by a prospective contractor in response to an invitation to tender. The client has a central role to play in this process.

Invitation to tender

Depending on the size of the project and the chosen procurement route the invitation to tender might be for one single contract or for a series of subsidiary contracts. For example, there might be a main construction contract (perhaps including design by the contractor), supplemented by separate contracts the demolition of existing buildings on the site and for the design, installation and commissioning of specialist equipment, such as cold rooms; to be installed after the building shell has been completed.

There are numerous approaches to tendering, but it is common practice for the client to require prospective tenderers to respond to a published advertisement by completing a pre-qualification questionnaire; in addition there may be pre-tender interviews. This process enables the client to prepare a short list of contractors with relevant experience and expertise and it reduces inefficiency and wasted effort. The alternative is an 'open' tender process, but this can result in an excessive number of tender offers, some of which will come from wholly unqualified contractors.

An invitation to tender might include:

- A letter of invitation to tender.
- The form of tender.
- Description of the scope of the works.
- Preliminaries; this is a document which describes the method and circumstances of the works – for example, restrictions on working hours – which may affect the offer price.
- Contract conditions.
- A tender pricing document.
- A drawing schedule.
- Design drawings.
- Specifications.
- The design risk assessment.
- Criteria to be used for tender evaluation and selection of the successful bidder.
- Process for reporting tender results.

Ideally, tender documents should be broken down into a series of clearly defined packages (even if there will only be one main contract), each with its own design drawings and specifications suitable for issue to potential sub-contractors by the main contractor. This makes it easier for the contractor to price and easier for the client to compare tender offers.

Queries and clarifications

There are likely to be mid-tender discussions with the bidders to clarify issues that might otherwise lead to inaccurate tenders. Adequate time needs to be allowed for this process so that the problems raised are fully resolved and necessary changes are made to the tender documents; the resulting tenders will be better and more accurate and this is likely to save time and money later on.

It is important that every clarification and amendment is sent to every tenderer. It is equally important not to reveal any confidential information divulged to the team during discussions with individual contractors.

Tender submission

At the end of the designated tender period the tenderers will submit their offers. The precise content of the submitted information will vary considerably depending on procurement route and the tender requirements, but it must include a completed tender

return form, a pricing document, details of the construction programme, details of the project management structure and key project personnel. In addition there should also be supporting material such as plant and labour resources, references, etc. The complete package of materials must be sufficient to enable the client to evaluate the tender.

Tender evaluation

The client's tender board will evaluate the tenders received, preferably against pre-defined selection criteria[18]. It may be necessary to conduct further interviews and negotiations with the preferred bidder, resulting in further adjustment of the tender documents and the submission of a revised tender.

Two-stage tendering

Two-stage tendering allows early appointment of a contractor, before completion of all the information that the tenderers need in order to offer a fixed price.

In the first stage, a limited appointment is agreed, allowing the contractor to begin work. In the second stage, a fixed price is negotiated for the contract. Two-stage tendering is often used for design-and-build projects. In this case, the contractor will tender a fee for designing the building and provide a schedule of rates that can be used to establish the construction price during the second stage tender.

2.4.7 The client's role during the construction stage

The construction stage starts when the contractor takes possession of the site from the client in order to carry out the works described in the construction contract. When the works are complete, the client's contract administrator certifies that the work is complete and the site is handed over to the client.

Generally, construction does not begin immediately after the contractor has been awarded the contract, but is preceded by a mobilisation stage. During this stage the contractor plans the works, places sub-contracts, manages specialist design, carries out necessary surveys and so on.

The client's chief responsibilities during the construction phase include:

- Attending formal site meetings.
- Making timely decisions on any proposed design changes, cost savings and additional expenditure to the extent that these issues arise.
- Making interim payments to the contractor in accordance with the contract conditions, against valuations submitted by the contractor and checked by the contract administrator.

The final payment to the contractor is generally made up to a year after handover at the end of a 'rectification period', during which the contractor remains responsible for dealing with any defects that may arise.

2.4.8 Commissioning and handover

The handover of the building to the client takes place once the contract administrator has confirmed that the works defined in the contract are sufficiently complete to enable the

[18] The lowest priced offer is not always the best offer.

client to occupy and operate the facility. At this point the client must receive all the information needed to operate the building safely and effectively, including the Operation and Maintenance Manual – see Technical Supplement: *Maintenance of storage facilities*.

Having accepted the site from the contractor, the client then has to prepare the building for occupation and operation. As noted in 2.4.2, the details of this procedure should be agreed early on in the project planning stage and the commissioning team should be nominated so that they can participate in the design process.

2.5 Procuring cold rooms and freezer rooms

Cold rooms and freezer rooms may be procured as component elements of a new building project. They may also be installed in an existing warehouse, either to replace time-expired equipment, or to meet a new or expanding need. In both these situations it is important to follow a systematic procurement process, similar to the one described above, in order to ensure that suitable equipment is specified and that it is correctly installed and commissioned. The WHO PQS website includes a set of specifications and verification protocols which can assist with this task[19]. These documents cover panel-based rooms that are erected inside a new or existing building enclosure. In very large cold stores, the insulated enclosure may also form the outer envelope of the building. Guidance on these larger structures can be found in the following reference[20].

[19] See: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=15 and click on 'category documentation'.

[20] Thermal Panel Manufacturers Association. *General specification for the design and construction of cold store envelopes incorporating prefabricated insulating panels.* September 2006. http://www.tpma.org.za/Images/Pdf%27s/GENERAL%20SEPCIFICATION1.pdf

References

There is a huge amount of reference material relating to the topics covered in this supplement. The following is a small selection, with the emphasis on free web-based guidance materials.

- Abu Dhabi Urban Planning Council. *The Pearl Rating System for Estidama.* http://estidama.upc.gov.ae/template/estidama/docs/PBRS%20Version%201.0.pdf
- American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. *Advanced Energy Design Guide for Small Warehouses and Self-Storage Buildings.* Atlanta, GA. 2008. https://www.ashrae.org/standards-research--technology/advanced-energy-design-guides/30-percent-aedg-free-download
- Angelo LB, Ferreri SP. *Assessment of workflow redesign in community pharmacy.* Journal of the American Pharmacists Association. 2005; 45:145-150. http://www.ncbi.nlm.nih.gov/pubmed/15868756
- Baker, P. (Ed). *The Principles of Warehouse Design.* The Chartered Institute of Logistics and Transport in the UK. Third edition. 2010
- Battersby, A., Garnett, A. *How to estimate warehouse space for drugs.* WHO/DAP/93.3. WHO, 1993. http://apps.who.int/medicinedocs/documents/s19159en/s19159en.pdf
- BREEAM. *International New Construction Technical Manual.* 2013. Available free by registering online at www.breeam.org
- Center for Drug Evaluation and ResearchJohn Snow, Inc. | DELIVER in collaboration with the World Health Organization. *Guidelines for the Storage of Essential Medicines and Other Health Commodities.* Arlington, Va. 2003. http://apps.who.int/medicinedocs/pdf/s4885e/s4885e.pdf
- Crichton, B. *Keep in a cool place: exposure of medicines to high temperatures in general practice during a British heatwave.* JR Scc Med 2004; 97: 328-329. http://www.epela.net/epela_web/document_lib/Keep_in_a_cool_place.pdf
- Designing Buildings Wiki http://www.designingbuildings.co.uk
- Jet Environmental video. *Pharmaceutical Warehouse Temperature Control* http://jetenvironmental.com/pharmacetical-warehouse-temperature-control
- John Snow, Inc. | DELIVER in collaboration with the World Health Organization. *Guidelines for Warehousing Health Commodities.* Arlington, Va. 2005. http://apps.who.int/medicinedocs/documents/s16875e/s16875e.pdf
- Link51. *Racking & Warehouse Storage Guide.* http://www.ribaproductselector.com/Docs/5/04685/external/COL422885.pdf
- Log Cluster Logistics Operational Guide. *Warehousing and Inventory Management* http://log.logcluster.org/mobile/response/warehouse-management/index.html

- Management Sciences for Health. MDS-3: *Managing access to medicines and health technologies*. Kumarian Press, Arlington, VA. 2011. Available on-line at: http://www.msh.org/resources/mds-3-managing-access-to-medicines-and-health-technologies MSF. PSF-CI Pharmaceutical guide. *How better to manage pharmaceutical warehouses*. Médecins Sans Frontières, 2003. http://dmsic.moph.go.th/download/pharmwarehouse.pdf
- NHS National Patient Safety Agency. *Design for patient safety: A guide to the design of the dispensing environment*. Edition 1, 2007 http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60143&type=full&servicetype=Attachment
- Pharmacens Sans Frontières. *PSF-C1 Pharmaceutical guide: How better to manage pharmaceutical warehouses*. March 2003. http://dmsic.moph.go.th/download/pharmwarehouse.pdf
- Richards, G. *Warehouse management.* The Chartered Institute of Logistics and Transport (UK) and Kogan Page, London, 2011.
- Rushton, A., Croucher, P., Baker, P, *The handbook of logistics and distribution management: Third edition.* The Chartered Institute of Logistics and Transport (UK) and Kogan Page, London, 2008.
- Target Zero. *Guidance on the design and construction of sustainable, low carbon warehouse buildings.* Report v2.0 June 2011. http://www.steelconstruction.info/index.php?title=Special:ImagePage&t=Warehouse+guidance+doc+v2.pdf
- Thermal Panel Manufacturers Association. *General specification for the design and construction of cold store envelopes incorporating prefabricated insulating panels.* September 2006 http://www.tpma.org.za/Images/Pdf%27s/GENERAL%20SEPCIFICATION1.pdf
- U.S. Food and Drug Administration. *Guidance for Industry Q1A(R2) Stability testing of New Drug Substances and Products.* Revison 2, November 2003> http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm128204.pdf
- US Green Building Council. *Leadership in Energy and Environmental Design (LEED).* http://www.usgbc.org/leed/certification
- WHO *PQS catalogue* http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorylist.aspx
- WHO Specification and verification protocols for cold rooms and freezer rooms. http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorypage.aspx?id_cat=15
- WHO Technical Report Series, No. 908, 2003. *Annex 9: Guide to good storage practices forpharmaceuticals.* http://apps.who.int/prequal/info_general/documents/TRS908/WHO_TRS_908-Annex9.pdf

- WHO Technical Report Series No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical* http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf

Annex 1 – Briefing documents

Briefing documents evolve over the life of a project and require specialist input from the consultant team. An experienced client may be able to prepare a detailed brief at a very early stage, without the need for a great deal of further development. On the other hand, an inexperienced client may need the help of an independent client adviser to prepare a strategic brief; this can then be developed further with the help of the consultant team[21].

A1.1 Statement of need

A statement of need is the client's very first attempt to describe the possible requirements. This may be drawn up before any final decision has been taken to proceed with the project, or to define precisely what form the project might take.

A1.2 Strategic brief

The strategic brief is written by the client and provides sufficient information about the project to allow the appointment of a suitable consultant team.

The strategic brief is then further developed by the client with the benefit of feedback from the consultant team. It will then describe the client's requirements in sufficient detail for feasibility studies and option appraisals to be carried out.

A1.3 Project brief

The project brief is a development of the strategic brief and is the key document upon which the design will be based. It evolves through the project brief stage and the concept design stage with the benefit of information gained from consultations with the client and other stakeholders and ongoing design development. It is 'frozen' at the end of the concept design stage and any further changes are subject to formal change control procedures.

The project brief is a formal statement of the objectives and functional and operational requirements of the finished project. It should be prepared in sufficient detail to enable the project team to prepare detailed designs and specifications; it is an essential reference for the team.

In the case of *design and build* or *PPP* contracts the project brief is a key component of the project execution plan. This is further developed at tender stage into an output-based specification, a document which focuses on the client's desired outputs in business terms, rather than providing a detailed technical specification of how the service is to be provided; this allows providers to propose innovative solutions that might not have occurred to the client.

[21] Heavily adapted, with permission, from material at http://www.designingbuildings.co.uk relating to brief development.

Annex 2 – Alternative contracts

The following sections describe three forms of building procurement contract, with risks and responsibilities passing increasingly from the client to the contractor[22].

A2.1 Lump sum contract

A lump sum contract is the traditional means of procuring construction, and it remains the most common form of construction contract. Under a lump sum contract, a single 'lump sum' price for all of the works is agreed before the works begin, although this figure can vary, as described below. A truly 'fixed' price contract would not necessarily be in the interests of the client as it would require that the contractor price risks over which they may have no control, and which might not arise.

A lump sum contract is generally appropriate where the project is already well defined at the time when tenders are invited, and subsequent design changes are unlikely. This means that the contractor is able to accurately price the risk they are being asked to accept. Lump sum contracts are less suitable where speed is important, or where the nature of the works is not well defined.

A lump sum contract does not give all the project risk to the contractor, but it does give the client some certainty about the likely cost of the works. However, the price of a lump sum contract can change and there are mechanisms for varying the contract sum, including:

- *Variations:* These are changes in the nature of the works. Most contracts will contain provision for the contract administrator to issue instructions to vary the design, quantities, quality, sequence or working conditions.
- *Relevant events:* A relevant event may be caused by the client (for example failure to supply goods or instructions), or may be a neutral event (such as exceptionally adverse weather) and may result in a claim for loss and expense by the contractor.
- *Provisional sums:* An allowance for a specific element of the works that is not defined in enough detail for tenderers to price.
- *Fluctuations:* A mechanism for dealing with inflation on projects that may last for several years. The contractor bases the tender on current prices and the contract terms make provisions for the contractor to be reimbursed for price changes over the duration of the project.
- *Other payments:* Including fees for building inspections and payments to sub-contractors and suppliers.

The better defined the works are when the contract is agreed, the less likely it is that the contract sum will change.

[22] Adapted, with permission, from material at http://www.designingbuildings.co.uk relating to building contracts.

A2.2 Design and build

Design and build is a generic term describing a procurement route in which the main contractor is appointed to design and construct the works. This is different from the traditional lump sum contract, described above.

Design and build can appeal to clients as it gives a single point of responsibility for delivering the entire project. Some consider that it is only appropriate for simple projects, where design quality is not the main consideration.

The contractor can either be appointed to carry out all of the design work. Alternatively, if the client wishes to have greater influence over the design, a concept design and outline (or performance) specification can be prepared by a consultants employed by the client; the contractor is then appointed to complete the design and carry out the construction.

The contractor may use their own in-house designers to design the building, or they can appoint consultant designers. Alternatively, the client's own designers can be re-employed by the contractor to complete the design.

If the contractor is appointed at the outset of the project they can contribute to the development of the design from the beginning. Typically this involves a two-stage process. In the first stage, the contractor is selected on the basis of a fee, preliminaries, overheads and profit. They then work with the design team (who may be employed either by the contractor or by the client at this stage) to develop the design. On the basis of this design, a fixed price is negotiated for the construction stage.

Design and build contracts can be awarded on a fixed-price, lump-sum basis. However, price certainty is then dependent on not making any design changes. Such changes may be expensive because the prices charged by the contractor for those changes will no longer be subject to competition. It is very important therefore that the client gives a great deal of consideration to the preparation of employer's requirements. If they have not appointed their own design team, they may wish to appoint independent client advisers to help them prepare this document. Similarly if the clients original design team is transferred to the contractor during the construction stage, the client may want to appoint an independent client adviser to review contractor's design proposals, administer the contract and monitor works on site.

A2.3 Design, build, finance and operate

An example of a design build finance and operate procurement route is a Public Private Partnership (PPP).

A single contractor, with design, construction and facilities management expertise, as well as funding capability, is appointed to design and build the project and then to operate it for a period of time. The contractor finances the project and leases it to the client for an agreed period (perhaps 30 years) after which the development reverts to the client.

As this is a very long-term relationship, entered into before any design work is undertaken, it is extremely important that the client defines their requirements very carefully, in particular the quality of service that is required and how it will be judged. A great deal of risk is given to the contractor, however the price they offer will reflect this.

Revision history

Date	Change summary	Reason for change	Approved