**Lebanese Red Cross**

**Design Guidelines**

 **Antelias Blood Center**

1. **Introduction**
2. **Purpose of the design guidelines**

Design Guidelines aim to serve as a tool to develop an appropriate design brief with the building design teams. They should be read and used in conjunction with relevant national and local standards and applicable guidelines. Ministry of Public health and BTS policies regarding the provision of a safe blood supply must be taken into consideration.

1. **Description of the guidelines**

 The design guidelines are divided into two sections:

(1) *functional guidelines*, including schedules of spaces, and

 (2) *design guidelines*.

The schedules of spaces list all the spaces in the facility, while the functional guidelines explain the relationship between units and between spaces within these units. Planning must ensure that all the scheduled spaces agree with the specified size and that spaces are located so they relate to one another to support the functions described in the functional brief.

Once the overall plan has been developed, each space or room must be planned in detail, usually at a scale of 1:50, to ensure that the equipment and furniture can fit in the space and that they are laid out in a way that supports efficient and safe work practices.

**Functional guidelines and schedules of spaces**

The functional guidelines describe the role and function of a blood center and the major issues to be considered when designing such a facility. It then describes the operation and function of each unit or department in the facility, including their scope of services, workload, major spaces, building fabric and engineering services required to provide the specified operation and function. Schedules of spaces are provided for each unit or department for an average workload of 200 units/day.

These schedules identify the required area for each room or space within each unit and the number of rooms or spaces required. They also include a circulation allowance to cover corridors and stairs connecting these spaces. In preparing the schedules of spaces, all areas are measured in square meters (m2). All areas are measured to the center line of the walls enclosing the room or space. These walls are assumed to be a nominal 100 millimeters (mm) thick.

**Design guidelines**

The design guidelines set out the requirements of the building fabric (not the function or role of activities happening within it). It describes the physical performance required for each building element (doors, walls, floors, etc.) and engineering services (power, lighting, air conditioning, etc.).

**Equipment Schedules**

It is essential that the design team produces them. These schedules are needed to ensure that: • spaces are large enough to house the equipment

• the structure is adequate to support the equipment both in its installed location and along its movement path during installation or removal

• doorways including lift doors and corridors are large enough (measuring both height and width) to permit the movement of equipment during installation or relocation

• adequate power is available for the equipment in its installed location

• air conditioning is designed to cope with the heat generated by some pieces of equipment

Equipment schedules must list each piece of equipment by room, specifying:

• equipment name, brand and model number

• critical dimensions

• weight

• power requirements

• services requirements, including gas, water supply and drainage

• heat output

• location (floor, trolley or bench mounted).

1. **Functional Guidelines**
2. **Blood Centre**

The blood center is the location for the collection, receipt, processing, testing, storing and distribution of blood.

1. **Planning issues**

***Blood Storage***

Blood and blood products are normally stored in one of two ways: in refrigerator and freezer cabinets or in walk-in cool rooms and freezer rooms. Choosing one of these two methods for the primary storage of blood and blood products is central to the operation of the blood center and should only be made after a detailed review of local circumstances.

* **Refrigerator and freezer cabinet**

• Failure or breakdown of one cabinet only affects the contents of that particular cabinet.

• If a biomedical engineer is not available to maintain defective cabinets, broken cabinets may not be repaired and over time, total storage capacity at the blood center will decline.

• Parts required in cabinet repair and maintenance may not be readily available as many manufacturers use their own unique components.

• Cabinets require more space to store a given amount of blood than walk-in cool rooms and freezer rooms.

* **Cool rooms and freezer rooms:**

• Cool rooms and freezer rooms are similar to those used in the food and hotel industries. Therefore, skilled maintenance staff and component equipment are usually available in most towns and cities.

• Cool rooms and freezer rooms require less space to store a given volume of blood than refrigerator and freezer cabinets.

• Total failure of a cool room or freezer room that cannot be repaired quickly may lead to the total loss of all contents. This could result is a critical disruption to the supply of blood in the health system. As part of the centers risk management, cool rooms and freezer rooms in both the processing and inventory and distribution areas should have excess capacity to allow emergency short-term storage of blood from a broken cool room or freezer room. In cool rooms and freezer rooms, blood bags are usually held in wire mesh baskets that are stored on wire mesh shelving units. The height of the highest shelf should not be more than 1350 mm above the floor because of the weight of the blood bag baskets that must be lifted on and off the shelves.

***Blood Flow***

The planning of a blood center should permit the movement of blood in one direction through the center. The process flow for blood should be planned so that there is minimum re-tracing or crossing of paths at different points in the handling process.

***Hours of Operation***

The Inventory and Distribution areas of a blood center will operate 24 hours, seven days a week to ensure that blood is available to hospitals at all times, and particularly in the case of emergencies. Other areas of the blood center will operate during normal business hours. The design of the center should allow for “locking down” areas that are closed, while maintaining access to those areas that are operating. Security and staff facilities should be designed to suit the hours of operation of each department within the blood center.

***Blood and sample registration***

Real-time control of all blood and blood sample movement into and out of the center is required to ensure accurate documentation of all samples and products through processing, testing and storage and to ensure operational efficiency All blood and blood products entering the blood center should pass through a central reception and/or registration point.

Similarly, all blood distributed from the center should be documented at a central dispatch registration point. All blood disposed on site should be documented at a central disposal registration point.

***Biosafety***

Biosafety policies must be in place for protection of staff and transfusion recipients. Personal protective equipment should be used as appropriate and all blood and blood products should be considered infectious unless and until verified tests prove otherwise. Immediately accessible hand-washing facilities with hot and cold water should be provided in all areas where blood or blood products are handled.

***Staff Amenities***

Staff toilets and wash basins should be easily accessible from all work areas. Locker rooms and staff lounges or tea rooms are decentralized within individual units. Appropriate facilities should be provided for staff working in 24-hour operations, including security staff and drivers. Staff working in Inventory and Distribution should preferably not have to leave the unit to access staff amenities.

*Occupational health and safety*

The blood center should be designed to ensure the health and safety of staff and visitors. Materials and finishes should be selected to reduce the chance of slipping or falls. All desks and work stations should be designed to depths and heights that allow safe and comfortable working conditions. The lowest shelf should be at least 150 mm high above the floor and the highest shelf should be no more than 1800 mm above floor level.

*Security*

A physically secure environment must be provided at the facility for staff. Access to all areas within the building where blood or blood products are handled or where confidential donor, patient or staff records are stored or accessed should be restricted to authorized BTS staff. Processes should be developed for biological security in all areas where blood and blood products are handled. Adequate space and facilities must be provided for the security staff.

*Stores*

A wide range of materials may be stored at a blood center, including records, consumables, blood storage containers and equipment for demountable collection centers. The center may store these materials for the national or regional blood service or just for the services provided by the center itself. All items and materials held at the blood center must be clearly identified and adequate space provided for storage.

*Vehicle parking*

On-site parking should be provided for the BTS mobile collection vehicles and blood transport vehicles. Parking spaces should be provided for BTS staff cars in accordance with local practice. All parking should be limited to designated areas.

*Engineering services*

Engineering facilities should be designed to be energy efficient, easy to maintain, well monitored and recorded and with low capital costs. It is important that the engineer is well informed of the condition of the facilities and can carry out prompt and effective preventive and corrective maintenance work.

*Building automation system*

Where technology and adequate trained staff are available, a building automation system (BAS) should be used to manage the facility. The BAS permits the remote monitoring and control of major pieces of engineering equipment and systems. This results in more prompt and reliable engineering services and efficient use of energy.

1. **Departments or units of the blood center**
2. **Production Unit**

**Concept:**

The Production Unit is responsible for the reception of all blood entering the blood center, its processing and storage.

The unit is co-located with the Inventory and Distribution unit and the testing Laboratories.

 **Scope of services**

This Processing Unit is responsible for:

 • Blood and blood sample reception and registration

• Blood component preparation

• quarantine storage and,

• labelling of verified blood prior to storage in the inventory and distribution unit.

The separation of processing activities from inventory and distribution activities is part of the organizational structure required to ensure the effective separation of untested from tested and verified blood and is considered critical for the assurance of the safety of blood components. This separation should be clear and strict.

**Workload**

The Processing unit should be designed to handle the specific workload of the blood center. As the number of blood units requiring processing will fluctuate from day to day reflecting local collection practice, the maximum daily number of blood units requiring processing will be greater than the average daily number of blood units requiring processing.

**Hours of operation**

Blood must be processed within defined time frames, according to the method of collection, conditions of temporary storage prior to processing, and the intended use of the blood.

**Location and Relationship**

The central blood reception area of the Processing unit should be located in an area with good access for delivery vehicles.

The processing unit should have good access to the laboratories through co-location. It is recommended that the Processing unit may be co-located with the Inventory and Distribution unit and the testing Laboratories.

**Workflow**

***Blood Reception***

All blood units and blood samples from collection facilities will be received at the central reception area.

Blood reception and registration should follow the blood center policy to permit the tracking of all blood and samples through the processing and testing system, with the capacity for “look back” and traceability.

***Component Preparation***

Whole blood units are separated into blood components for transfusion. Blood is usually separated into plasma, red cells and platelets. Additional activities including leucocyte filtration, and pathogen inactivation are also carried out as part of component preparation.

***Quarantine Storage***

After component preparation, blood components are held in temperature-controlled and quarantined storage prior to completion of testing and verification. The physical separation of quarantined and inventory blood for release is essential to the maintenance of a safe blood supply. The capacity of processing cool rooms should be a minimum of 2.5 times the average daily service load plus 50% to allow for variations in daily work load. The capacity of processing freezer rooms should be a minimum of 7 times the average daily service load plus 50% to allow for daily fluctuation.

***Labelling***

After testing verification, each blood component unit is labelled and issued to the Inventory and Distribution unit for inventory storage. Blood units not suitable for transfusion must be stored separately prior to disposal.

***Access and Security***

The Processing unit must be maintained as a secure work area. Visitors should only be permitted to enter if accompanied by an assigned staff member or if electronic or physically controlled access is available.

***Supply and Storage***

Consumables should be delivered directly to, and stored within, the unit.

***Functional Content of the Processing Unit***

Processing should include the following areas:

|  |  |
| --- | --- |
| Loading Dock | Delivery and dispatch truck parking and area to load and unload trucks. If space is available, delivery and dispatch functions should be separated |
| Reception  | Reception and registration of blood |
| Storage | Storage of consumables used in the unit. |
| Component Preparation | Processing blood in bags to be separated into components.  |
| Pathogen Inactivation | Pathogen inactivation for platelets |
| Plasma Freezing | Bags of plasma frozen in freezing cabinets for storage in freezer rooms and/or refrigerated storage equipment. |
| Quarantine Blood Storage | Controlled temperature storage (refrigerator and freezer) of blood components prior to the verification of test results and transfer to Inventory and Distribution storage or disposal |
| Verification | Labelling of verified blood components prior to transfer to Inventory and Distribution. |

***Waste Management***

Waste should be managed in accordance with established blood center policy.

***Housekeeping***

The unit should be cleaned in accordance with established blood center policy. The unit should have its own dedicated cleaning equipment to prevent the possible contamination of other areas with unverified blood.

***Schedule of Spaces***

If the unit must process blood for two or three shifts a day to meet the delivery schedule of the blood, then the processing space and offices for processing supervisors identified in the schedules of spaces may be adjusted downwards accordingly. Additional spaces will be required if preparation processes include blood irradiation, leucocyte filtration, and pathogen inactivation.

***Building Fabric***

Appropriate temperature and humidity levels need to be maintained for staff comfort and for the integrity of blood components and materials. Attention should be given to selecting materials for their durability, fire safety and ease of cleaning and disinfection. Similarly, the detailing of the building fabric and fittings should permit ease of cleaning and disinfection. Material selection shall conform to good manufacturing practice (GMP) requirements. Natural light and an external view from all work areas are desirable.

***Engineering Services***

* Mechanical ventilation Exhaust ventilation for the toilet and staff lounge (tea-making facilities) should be provided.
* Air conditioning All processing spaces and rooms with refrigerated cabinets or freezers should be air conditioned. Office spaces should be air conditioned in accordance with local practice and standards.
* Cool rooms and freezers Walk-in 4ºC cool rooms and walk-in -20ºC freezers for large processing units, or freezer and refrigerator cabinets for smaller units, should be provided. Walk-in (20ºC-24ºC) controlled environment rooms or cabinets are required for platelet storage. All walk-in cool rooms and freezers, or stand-alone freezers and refrigeration cabinets, are to be monitored by the building automated system (BAS) where provided. Emergency procedures for access control to these cool or cold rooms in case of power or refrigeration failure should be developed. All walk-in freezers, cool rooms, and freezer or refrigerated cabinets should have alarms that register locally, in inventory and distribution (if staffed 24/7) and in the engineer’s office.
* Electric lighting the use of natural light should be maximized; artificial lighting should be provided to the level and type appropriate for the work to be performed. Generally, a minimum of 200 lux for the processing area and 250 lux for storage areas are required. Emergency lighting should be provided in the event of power failure and designed in accordance with current regulations.
* General Power outlets and power supply should be provided to suit all equipment with an additional allowance for mobile equipment and the addition of new pieces of equipment. Reference should be made to the Schedule of Equipment when designing the power layout.
* Standby power in the event of power failure, standby power from the emergency diesel generator should be provided for emergency lighting, all cool rooms, freezers and designated equipment.
* Uninterrupted power supply (UPS) UPS packs should be provided for all critical equipment. If a computer-based sample database is used, at least one computer should be connected to a UPS supply. A central UPS system may not be necessary.
* Security as the processing areas are to be secured, access should be strictly controlled. An electronic security system with proximity access cards is preferred.
* Water supply Hot and cold water should be provided as required to hydraulic fittings throughout the unit. Mains water should be tested and, if required, be pre-filtered prior to recirculation in the unit. Emergency showers and eye-wash units should be provided in accordance with relevant laboratory standards and codes.
* Filtered water High-quality filtered water should be provided to designated equipment from a central reverse osmosis water filtration plant.

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| --- |
| **Schedule of Spaces production-200 units’/day center** |
| Space  | Area | No. | Total  | Comments |
| Loading dock | 10 | 1 | 10 | Allow covered parking for 2 vehicles |
| Blood and Sample reception | 6 | 1 | 6 |  |
| Hand wash and gowning bay | 4 | 1 | 4 | At entry/exit to component preparation area |
| Component preparation and pathogen inactivation | 40 | 1 | 40 | Refer notes below |
| Plasma freezing area | 5 | 1 | 5 | Rapid plasma freezing |
| Quarantine refrigerator and freezer and platelets | 8 | 1 | 8 | Walk-in. Refer notes below |
| Verification and labeling | 10 | 1 | 10 |  |
| Waste holding | 4 | 1 | 4 |  |
| Circulation (30%) |  |  |  |  |

*Notes on schedule of spaces for processing unit*:

1) The areas given in these schedules are considered to be the minimum space requirements for the specified service capacities, but these areas should be reviewed to accommodate new or additional equipment and processes.

2) Additional specific spaces will be required if the unit is carrying out additional processes including:

• Blood irradiation

4) Refrigerated and freezer cabinet can be used instead of walk in cool rooms and freezers for plasma and red cell storage. When determining the space required for these cabinets allow a minimum of 75mm between cabinets and 50mm between cabinets and walls to permit heat dissipation.

5) Allow a minimum of 600mm between refrigerated centrifuges and between refrigerated centrifuges and walls to permit heat dissipation.

1. **Inventory and distribution**

**Concept**

The Inventory and Distribution unit is responsible for the inventory management and distribution of processed, tested and verified blood to users within the health system. The Inventory and Distribution unit should be co-located with and adjacent to, but separate from the Processing unit. The separation of inventory and distribution from processing is required to ensure the effective separation of untested and verified blood.

**Scope of Services**

The Inventory and Distribution unit will:

• plan and manage inventory

• store inventory blood

And

• Release and dispatch verified blood and blood products to users.

**Workload**

The Inventory and Distribution unit should be designed to store and distribute the expected workload.

***Hours of operation***

Staff should be available to respond to requests (by telephone, e-mail or other means) 24 hours a day, seven days a week, to enable blood dispatch whenever required. This may be achieved by staffing the unit for the full 24 hours or by staffing the day/evening shifts only (when the demand for blood is highest) and having staff on-call at all other times. The use of on-call staff requires dependable communication between the unit and staff at all times.

***Location and Relationship***

 The Inventory and Distribution unit should have good access for dispatch vehicles. It should preferably be co-located adjacent to the processing/production unit.

***Workflow***

 Labelled (verified) blood products are received from the Processing unit and held in temperature-controlled release inventory stores. Upon request, either by telephone, or e-mail, blood from the release inventory stores is distributed to the users. Prior to release, records of each blood or blood component unit are rechecked to ensure laboratory verification. All release blood and blood units are documented and recorded. This service operates 24 hours a day.

***Blood Disposal***

 Blood held in inventory storage that has passed its use-by date must be disposed of in accordance with the blood center’s disposal policy.

***Access and Security***

The Inventory and Distribution unit must be maintained as a secure work area. Visitors will be permitted access only when accompanied by a designated staff member or if electronic or physically controlled access is available. Visitors and couriers will have access to the distribution desk but cannot enter the unit.

***Housekeeping***

The unit should be cleaned in accordance with established blood center policy.

The unit should contain the following areas:

|  |  |
| --- | --- |
| Verified blood storage | Controlled temperature release inventory storage of blood components after labelling and verification. Blood maybe stored in walk-in cool rooms and freezers or refrigerated and freezer cabinets |
| Communication center | Receives telephone, facsimile or e-mail requests from hospitals for blood and arranges dispatch |
| Dispatch  | Hospital-requested blood and blood products assembled and held, awaiting dispatch |
| Courier waiting | Waiting area for couriers collecting blood and blood product orders |
| Transport boxes | Storage of cleaned transport boxes and coolants |
| Staff toilets | Separate male and female toilets |

***Building Fabric***

 Appropriate temperature and humidity levels need to be maintained for staff comfort and for the integrity of blood components and material. Attention should be given to selecting materials for their durability, fire safety and ease of cleaning and disinfecting. Similarly, the detailing of the building fabric and fittings should permit ease of cleaning and disinfection.

Material selection shall conform to GMP requirements. Natural light and an external view from all work areas are desirable.

***Engineering Services***

*Mechanical ventilation*

Exhaust ventilation for the toilet and staff room (tea-making facilities) should be provided.

*Air Conditioning*

 Office spaces should be air-conditioned in accordance with local practice and standards. Dispatch area where blood orders are assembled and documented and any rooms with refrigerated cabinets or freezers should be air conditioned.

Comfort conditions should be maintained at:

• 240 C ± 20 C DB/ 50% RH ± 10% in summer

• 200 C ± 20 C DB/ 40% RH minimum in winter

*Cool Rooms and Freezers*

Walk-in 4ºC cool rooms and walk-in -25ºC freezers for large Inventory and Distribution units, or freezer and refrigerator cabinets for smaller units, will be provided. Platelet agitators with environmental controls will be provided. All walk-in cool rooms and freezers or stand-alone freezers and refrigeration cabinets are to be monitored by the BAS (where provided). Emergency procedure for access control to these cool or cold rooms in case of power or refrigeration failure should be developed. All walk-in freezers and cool rooms and freezer and refrigerated cabinets should have alarms that register locally and in the engineer’s office. The amount of blood and blood products required to be held in inventory storage will vary according to the amount of blood and blood products held in the hospitals served by the center. Typically, the capacity of inventory cool rooms and freezers will be a minimum of 7 times the average daily service load plus 50% to allow for variations in daily work load but this figure should be adjusted to suit local conditions.

*Electric Lighting*

The use of natural light should be maximized; artificial lighting should be provided to the level and type appropriate for the work to be performed. Generally, a minimum of 200 lux for the processing area and 250 lux for storage areas is required.

*Security*

 As the Distribution unit is to be secured, strictly restricted access control shall be provided. Electronic security system with proximity access cards is preferred.

*Water supply*

Hot and cold water will be provided as required to hydraulic fittings throughout the unit. Mains water should be tested and if required be pre-filtered prior to recirculation in the unit.

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| **Schedule of spaces****Inventory and distribution-200 units/day**  |
| **Space** | **Area** | **No.** | **Total** | **Comments** |
| Loading dock | 10 | 1 | 10 | Allow covered parking for one vehicle **(external)** |
| Release cool room for red cells and fractionated plasma products | 15 |  |
| Release freezer cabinets for plasma (-30°C) |  |
| Release store for platelets (20°C-24°C) |  |
| Communication room and Distribution work area  | 8 | 1 | 8 | Receive requests for blood and blood products from hospital. Manage dispatch of blood and blood products to hospitals. |
| Store  | 8 | 1 | 8 | Storage of cleaned refrigerated transport boxes |
| Dispatch waiting | 8 | 1 | 8 | For couriers collecting blood and blood products |
| Circulation (30%) |  |  |  |  |

Notes on schedule of spaces for the Inventory and Distribution unit:

1) The areas given in these schedules are considered to be the minimum space requirements for the specified service capacities, but these areas should be reviewed to accommodate new or additional equipment and processes.

2) The schedule is based on the unit operating on a 24-hour basis. The unit may be staffed throughout this period or be staffed during normal working hours, with staff available on-call at all other times.

3) Refrigerated and freezer cabinet can be used instead of walk-in cool rooms and freezers for plasma and red cell storage. When determining the space required for these cabinets, allow a minimum of 75 mm between cabinets and 50 mm between cabinets and walls to permit heat dissipation.

5) Staff facilities including toilets and tea rooms may be provided within the unit or centralized within the blood center, depending on BTS policy.

6) Refrigerated plant should be located outside the facility

1. **Laboratories**
2. **Concept**

*Scope of Services*

The testing laboratories conduct testing of donor blood for blood group serology and infectious disease markers, and in-process quality control testing for blood and blood products. The testing laboratories may also provide a range of investigative and diagnostic services for patient testing, including red cell reference laboratory activities, and pre-transfusion testing.

*Testing of Donor Blood*

Testing laboratories carry out automated and/or manual testing on donor samples for:

 • Blood group serology: determine ABO and Rh group; detection of unexpected antibodies to red cell antigens;

• Infectious disease markers: according to BTS policy and national regulations, donor blood must be screened for transfusion transmitted infections such as Hepatitis B, Hepatitis C, Human Immunodeficiency Virus, and other agents as appropriate, e.g. syphilis, parasitic diseases, and bacterial screening. Testing laboratories may also carry out confirmatory testing on samples with positive or reactive responses during screening.

*In-process quality control testing for blood and blood products:*

Testing Laboratories carry out quality control testing of blood and blood products according to BTS policies and quality control sampling plan, e.g. platelet yield, residual leucocyte count, hemoglobin content, haemolysis, sterility testing, etc.

The scope of service must be clearly defined to permit planning of these laboratories.

*Shared Facilities*

Space and equipment can be shared by more than one laboratory unit to improve efficiency and to avoid duplication.

*Laboratory Administration*

Provision of the administration infrastructure required to service the individual laboratory units and to integrate the laboratory services into the BTS.

*Workload*

The testing laboratories will be required to screen samples of all donated blood within their service area

*Location and Relationship*

It is recommended that testing laboratories should be co-located with the Processing unit. The testing laboratories must have direct access to the central blood reception area. Good communications between the testing Laboratories and Processing unit is essential. Sample transport between the Processing unit and the testing Laboratories should ensure sample integrity.

*Workflow*

The laboratory workflow follows a linear process after any sample has been catalogued. The workflow should allow for possibly contaminated materials to be separated from those materials that will leave the laboratory, i.e. the laboratory should be demarcated as “clean” and “dirty” (potentially contaminated) areas. Testing areas should be set up to follow the order in which equipment is used. Results should be processed away from the bench and any dirty materials that move to the clean processing area protected by a clean sleeve.

*Blood Samples*

Blood sample reception and registration should follow the blood center policy to permit the tracking of all the samples through the testing system with the capacity for “look back” and traceability.

*Access and Security*

The laboratories will be maintained as a secure work area. Access to non-staff members will be permitted only when approved and/or when accompanied by a designated member of staff.

*Supply and Storage*

Only small quantities of flammable liquid and other dangerous reagents are to be stored in the laboratories. These are to be kept in appropriate storage cabinets that will be topped up as required from the external bulk reagent store.

*Waste Management*

Waste should be managed in accordance with established blood center policy.

*Housekeeping*

The unit should be cleaned in accordance with established blood center policy. The unit should have its own dedicated cleaning equipment to prevent the possible contamination of other areas with unverified blood. Glass washing and clean-up Glassware, instruments, etc. will be washed or sterilized within the unit in accordance with the relevant infection control standards and manufacturers’ instructions.

*Building Fabric*

Attention should be given to selecting materials for their durability, fire safety and ease of cleaning and disinfecting. Similarly, the detailing of the building fabric and fittings should also permit ease of cleaning and disinfecting. Material selectio*n* should conform to GMP requirements. Bench materials should have smooth, non-porous surfaces that are not corrodible and are reagent-resistant. Natural light and an external view from all work areas are desirable.

*Engineering Services*

*Mechanical Ventilation*

Exhaust stacks for fume cupboards and biohazard cabinets are to be provided. The laboratory areas should be maintained at a negative pressure from the corridors and entrances to avoid the spread of harmful or unpleasant fumes into areas adjoining the laboratories.

*Air conditioning*

All laboratory working spaces should be air conditioned. Laboratory comfort conditions should be maintained at:

• 240 C ± 20 C DB/ 50% RH ± 10% in summer;

• 200 C ± 20 C DB/ 40% RH minimum in winter.

 Office spaces should be air conditioned in accordance with local practice and standards. Differential air pressure should be maintained as required to maintain air quality in clean environments.

*Cool rooms and freezers*

Walk-in 4ºC cool rooms and walk-in -25ºC freezers or freezer and refrigerator cabinets will be provided for products and/or reagents and sample storage. All walkin cool rooms and freezers or stand-alone freezers and refrigeration cabinets are to be monitored by the BAS (where provided). Emergency procedure for access control to these cool or cold rooms in case of power or refrigeration failure should be developed. All walk-in freezers and cool rooms and freezer and refrigerated cabinets should have alarms that register locally, in the Inventory and Distribution unit if staffed 24/7and in the engineer’s office. Ample outdoor air should be available for the air-cooled condensing units for these rooms.

*Lighting*

The use of natural light should be maximized; artificial lighting should be provided to the level and type appropriate for the work to be performed. Generally, a minimum of 500 lux for laboratories and 250 lux for storage areas is required. Emergency lighting should be provided in the event of power failure and designed in accordance with current regulations. Local task lighting may be provided where the detailed nature of the tasks being carried out requires a higher level of illumination.

*General Power*

Power outlets and power supply should be provided to suit all equipment with an additional allowance for mobile equipment and the addition of new pieces of equipment. Reference should be made to the Schedule of Equipment (prepared by the design team recording the specific equipment requirements for each particular center.) when designing the power layout.

*Standby Power*

 In the event of power failure standby power from the emergency diesel generator shall be provided for emergency lighting, all cool rooms, freezers and designated equipment.

*Uninterrupted Power Supply*

UPS packs should be provided for all critical equipment. If a computer-based sample database is used, at least one computer should be connected to a UPS supply. A central UPS system will not be provided.

*Gas Supply*

Gases will be reticulated in the ceiling space from the central gas bottle store to bench or wall outlets according to local standards and regulations. All spaces where liquid nitrogen is handled should have oxygen level alarms that register locally and in the engineer’s office. Bottled gas manifold and cylinders are monitored for low-level and shut-off alarms. Local and remote alarms at the engineer’s office are to be provided. These spaces should have a window extending down to floor level to permit full observation at all times of staff working in the room by staff in the laboratory areas.

*Security*

Access to the laboratory areas should be restricted to authorized staff. Electronic access control with proximity card system is preferred. Where a proximity access card system is not available, keypad locks or key-operated locks with emergency exit hardware should be used.

*Water Supply*

Hot and cold water will be provided as required to hydraulic fittings throughout the unit. Mains water should be tested and if required, filtered prior to reticulation in the unit. Emergency showers and eyewash units should be provided in accordance with relevant laboratory standards and codes. Filtered water High-quality filtered water should be provided to designated equipment from a central reverse osmosis water filtration plant..

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| --- |
| **Schedule of Spaces****Laboratories**  |
| Space | Area | No. | Total | Comments |
| **Specimen reception and preparation** | 6 | 1 | 6 |  |
| Testing immunohematology | 15 | 1 | 15 | Maybe all manual or mixture of manual and automatic testing |
| Reagents and samples refrigerators and freezers | 8 |  | 8 |  |
| Gowning and preparation | 5 | 1 | 5 | Entry to clean room |
|  Testing serology | 40 | 1 | 40 | Maybe all manual or mixture of manual and automatic testing |
| Store/ staff room/kitchen | 20 | 1 | 20 | For all employees of the 3 section: distribution, testing and preparation |
| Toilets staff | 2.5 | 2 | 5 | For all employees of the 3 section: distribution, testing and preparation |
| Cleaning room | 4 | 1 | 4 |  |
|  |

1. Blood collection

*Concept*

Blood collection centers are facilities for blood donation in fixed or permanent locations. They are the first point of contact between the donor and the BTS.

*Scope of services*

(1) Screen potential donors.

(2) Collect blood from eligible donors.

(3) Supervise donor recovery.

 (4) Check and store donated blood prior to dispatch, to the testing and processing facility.

 (5) Manage donor results.

*Location*

Appropriate parking is essential. Building fabric Daylight should be maximized throughout the facility, particularly in donor areas. As the BTS becomes more reliant on voluntary donors, it is important that the collection facility design is pleasant and non-clinical for the donor, and that it enhances the donation experience. Open planning should be maximized to improve staff’s ability to observe donors. Interview rooms should be constructed to ensure visual and acoustic privacy. All spaces where blood is handled or materials are stored should conform to relevant standards and manufacturers’ instructions.

***Functional Content of the collection Unit***

A static collection center facility should provide the following areas:

|  |  |
| --- | --- |
| Waiting area |  |
| Reception area |  |
| Interview rooms | for collection of confidential and medical information and physical examination |
| Donation area | Space for couches and adjacent consumables storage.  |
| Checking/holding | Physical checking of collected units and donor samples prior to transport to laboratory or holding facility respectively |
| Post donation care and refreshment area | Space for donor treatment and recovery in case of an adverse reaction during or after donation. Post-donation lounge for donor recovery and refreshment with accommodation for observation by staff |
| Staff Area | Multi-purpose staff lounge and tea room. Offices Facility manager and other administrative staff |
| Store | Supplies for donor screening, haemoglobin testing, blood collection, etc |
| Cleaning room | Storage of cleaning equipment and waste and clean materials. |
| Toilets | Toilets for staff and donors. |

Engineering services

*Heating and air conditioning*

Heating and cooling should be provided in all functional areas and consumable stores. The air handling unit for this area should be independent of the blood processing and laboratory areas. Comfort conditions should be maintained at: • 240 C ± 20 C DB/50%RH ± 10% in summer • 200 C ± 20 C DB/40% RH minimum in winter Mechanical ventilation will be required for the toilets and for the food preparation area in the donor lounge.

*Electrical system*

Adequate power should be provided for all engineering services. Standby power should be provided for at least half of the lighting and to all of the electrical equipment in the donor areas. Residual current device (RCD) protection should be provided to equipment connected to donors. Warm, colour-corrected lighting should be installed in all donor areas (minimum 320 lux), including the donor treatment area. In case of an emergency, staff-activated medical and panic alarms should be installed in all areas; it is recommended that annunciators should be located at the reception area, manager’s office and checking area.

 *Data*

Where computer systems are provided, it is recommended that a structured cabling system using UTP Category 5E cables should be provided. Interchange between voice and data outlets should be made possible. Where electronically based donor records are used, data/voice outlets should be placed in all workstations. Where clocks are used they should be battery operated. In facilities providing apheresis services, uninterrupted power supply (UPS) must be installed to all apheresis couches.

*Fire protection and essential services*

Fire protection equipment including fire hydrants, hose reels, automatic sprinkler system, fire detection system / and emergency lighting should be provided in accordance with local regulations.

|  |
| --- |
| **Schedule of Spaces****Collection-200 units/day** |
| Space | Area | No. | Total | Comments |
| Waiting area | 10 | 1 | 10 |  |
| Reception area | 10 | 1 | 10 |  |
| Interview rooms | 8 | 1 | 8 |  |
| Donation area | 20 | 1 | 20 |  |
| Checking/holding | 8 | 1 | 8 |  |
| Post donation care and refreshment area | 12 | 1 | 12 | . |
| Staff Area | 12 | 1 | 12 |  |
| Store | 15 | 1 | 15 |  |
| Cleaning room | 5 | 1 | 5 |  |
| Toilets | 2.5 | 2 | 5 |  |
|  |

1. **Design Guidelines**
2. **Facility Planning and Design-General Considerations**

The design of the blood transfusion facility should provide an environment that is

 (1) Attractive to the public, and

(2) Safe and efficient for staff.

The planning of the facility should provide appropriate areas and relationships between spaces and clearly defined open and secure areas. Circulation routes should be clear and direct while providing appropriate traffic separation.

1. **Good Manufacturing Practices (GMP)**

The implementation and enforcement of Good Manufacturing Practices (GMP) in blood centers is considered a priority tool to minimize the risk of currently known and emerging bloodborne diseases. The adherence to GMP guidelines in the design of blood center facilities is essential to ensure that the collection and manufacturing environment will allow the production of blood and blood products of consistent quality. The center will be compliant to AABB guidelines for premises

1. **Building Elements Substructure**

*Superstructure*

Space between workstations and laboratory benches should be 1.5m or more. Clearance space between different working areas should be ≥ 3m

*Internal Walls and Partitions*

Internal walls and partitions should be designed to span vertically and horizontally and to carry any imposed loading. Consideration should be given to acoustic performance and fire resistance, where appropriate.

*Doors*

Laboratory entrance and exit doors width should be 120cm weatherproof. Internal doors width should be 90cm and should be selected as appropriate for their use and should include:

* Fire-rated doors
* Smoke-sealed doors
* Acoustically rated doors
* Solid core doors in areas subject to heavy traffic and impact

Generally, door sizes should be:

* Width to accommodate any goods trolleys used in the area

Sizes of all doorways (clear width and height) including lifts doors should be sized to permit the movement and installation of all pieces of equipment. Door sizes should be checked against the Schedule of Equipment.

Door hardware, appropriately selected for use, should include:

* Self-closing closers for all fire and smoke doors
* Security access control for selected doors.

Preference should be given to proximity card readers. Door frames should be appropriate for door use. Pressed metal frames should be used on all fire doors and doors exposed to heavy traffic and impact. Door protection to minimum height of 900 mm should be installed to faces of doors exposed to heavy traffic or impact. Door protection may be sheet metal, sheet vinyl or other impact resistant sheet material.

*Wall Finishes*

Generally, wall finishes should be low maintenance and washable. In laboratories and processing areas, high-quality glossy paint is recommended or special coating systems should be used. Impervious materials such as glazed ceramic tiles or sheet vinyl should be used in wet areas, such as showers, and as splash-backs behind sinks and basins.

*Floor Finishes*

Generally, floor finishes should be low maintenance and easy to clean. In laboratories, processing areas, and all areas where blood is handled, flooring will be chemically resistant and one-piece constructions with coverings to the wall, seamless sheet flooring with fully welded joints such as sheet vinyl should be used. Tiled finishes are not recommended in these spaces as it is extremely difficult to clean and disinfect the joints between tiles. Floors to wet areas such as showers should be laid to fall and include an integral floor drain. Anti-slip tiles or anti-slip sheet vinyl should be used in these spaces. Floors to plant rooms, long-term bulk stores and workshops may be monolithic concrete. Monolithic concrete should be finished with a specialist concrete seal to prevent the generation of dust and to protect the slab against oil and solvent penetration.

*Ceiling Finishes*

Ceilings should generally be low maintenance and easy to clean. In clean areas including laboratories, processing areas, and all areas where blood is handled, ceilings should have a flush, seamless finish with a washable paint or specialist coating system. Flush-finished gypsum, plasterboard, or cement fiber sheet are typical of acceptable materials. Tiled finishes are not recommended in these spaces as it is extremely difficult to clean and disinfect the joints between tiles even if the tiles themselves are impervious. Lay-in mineral fiber or gypsum plasterboard tiles may be used in offices (outside clean areas), stores, meeting rooms and general spaces. Use acoustic tiles as appropriate to particular spaces.

*Ceiling Heights*

The following minimum ceiling heights should be used:

General 2.7m, Corridors 2.7m, locally 2.4m, Cool rooms 2.4m, Freezers 2.4m, Toilets & shower 2.4m, Stores 2.4m

*Corridor Widths*

All corridors on main building escape/exit routes should be designed in accordance with local regulations. Other corridors should have the following minimum clear width between walls: Generally, 2.0m – Offices 1.5m

Corridor dimensions (clear width and height) should be sized to permit the movement and installation of all pieces of equipment. Corridor sizes should be checked against the Schedule of Equipment.

*Furniture and Fittings*

Furniture and fittings should be constructed and finished with materials and details appropriate to their intended use. Finishes should be easy to clean and maintain. Benches with round countertops edges and corners in all areas, where blood is handled, including Processing unit and Laboratories, should have smooth, seamless, non-porous surfaces that are not corrodible and are reagent-resistant. Furniture and fittings used in wet areas or with in-set sinks or bowls should be constructed of waterproof materials. Shelves shall be with 2cm lips above shelf surface and 3.8cm shelf surface for stored materials. Height of sit-down workbenches and desks 78cm.

1. **Engineering Services**

 *Building Automation Systems (BAS)*

A BAS should preferably be used to manage the facility. The BAS permits the remote monitoring and control of major pieces of engineering equipment and systems. This results in more reliable engineering services and efficient use of energy.

*Heating, Ventilation and Air Conditioning*

Depending on the geographic location and climate condition of the blood center, heating or air conditioning may be required to ensure the correct environmental conditions is provided for the blood processing and testing purposes. The proposed conditions are:

• 22°c ± 2°c

• 50% ± 20% in summer

• 20°c ± 2°c

• 50% ± 20% in winter

 In offices and donor areas where comfort conditions may be desirable, heating and air conditioning systems may be provided to meet the following conditions:

• 24°c ± 2°c in summer

• 21°c ± 2°c in winter

A separate air conditioning plant should be provided for the processing and testing facilities and the office areas. Air conditioning systems should be zoned to maintain environmental conditions depending on zone orientation and exposure to solar heat gain.

*Environmentally Sustainable Design (ESD) Principles*

In designing an air conditioning or heating system, ESD principles should be considered for energy efficiency. Both passive considerations (e.g. building orientation, window location and shading, natural lighting, choice of glazing, construction of building envelop) and active devices (e.g. variable speed control for the chillers, economy cycle, chilled beam technology) should be considered in the design process. Solar hot water and power should be investigated. With the rapid developments currently happening in solar energy collection and power generation, these technologies are becoming progressively more economical and easier to maintain.

*Water-Cooled or Air-Cooled Air Conditioning System*

Since Legionella pneumophila (causative agent of Legionnaires’ disease) is a potential problem, an air-cooled instead of water-cooled air conditioning system should preferably be considered if possible.

*Ventilation*

For BSL2 laboratories, a specific pressure control scheme has to be put in place for virus and bacteria control purposes. Fresh air intake for the air conditioning system should be kept clear of the exhaust system to avoid short-circuiting of air path and should comply with local regulations.

Redundancy Provisions:

To ensure the maintenance of design conditions (air conditioning and refrigeration) in critical areas, it is advisable to provide some redundancy provisions.

 Redundancy provisions to be considered are:

• In a multi-chiller system, chillers may have Building Management System (BMS) controls to shed non-critical loads so that conditions in laboratories and the processing areas can be maintained when chiller failure occurs.

 • Alternatively, in a multi-chiller system if there is not a

BMS, an additional (or redundant) chiller may be provided that can be bought on stream in the event of chiller failure.

• Each cool room and freezer room should be provided with duplicate refrigeration systems. In the event of the failure of the primary refrigeration system, design conditions are maintained by switching over to the duplicate refrigeration system. During normal operations, the refrigeration systems should be alternated on a weekly or fortnightly basis to ensure effective equipment operation.

 • The refrigeration alarm system and front end software should be provided with a redundant CPU so that failure of one CPU will not affect the normal function of detecting and sounding alarms and continuous display of system operation at the front end.

*Electricity Supply*

The reliability of the local power supply should be checked with the local power supply authority. As some operations of the blood transfusion facility require reliable power supply (such as cool rooms and automatic blood testing equipment), dual high voltage supplies from different zone substations is preferred. A standby power supply system will be needed. The capacity of the standby power supply system will depend on the load that is required to maintain the critical functions of the facility. A load demand study should be carried out. The standby power supply can be in the form of a standby diesel engine generator set or gas turbine driven generator set. Generally, a diesel generator set is more suitable if the load is less than 2000 kVA.

Standby power should be provided to:

• All cool rooms and freezer rooms/blood storage devices

• All refrigerator and freezer cabinets

• 50% of general lighting

• Emergency lighting system

• Central alarm system

• Laboratories and Processing areas

 • Minimum number of chillers and pumps required to provide air conditioning to laboratories and processing.

• Basic ventilation to all areas other than Laboratories and Processing.

• Essential services including fire pumps, fire indicator panels, EWIS (early warning intercommunications system), fire detection systems and one lift to be used by fire authorities.

In designing a diesel generator system, a fuel storage tank should be considered, particularly in areas where delivery of fuel is unreliable. Normally the storage should be adequate for three days of operation. Acoustic control for the engine room and the flue needs to be considered to minimize the impact of noise on the neighbors.

*Power Quality Protection*

The incoming power supply to a blood center may be contaminated or unreliable to the extent that it can compromise the operation of the center by affecting critical pieces of equipment. Precautions should be taken to protect the center and critical equipment.

Power quality contamination can be caused by:

1. Power surges and sags, including fluctuation of incoming power supply voltage due to other external loads. Typically, where there is a large factory or industrial complex in the neighborhood that has machines with large power consumption, each time the machine is operated, large currents are drawn from the network causing the network voltage to drop. When some of these external machines connected to the network are taken off load suddenly, a surge in system voltage can occur.
2. Electrical receptacles above countertops within 1.5 – 1.8cm
3. Lightning surges. A lightning strike to an overhead line providing power to the blood center can cause a power surge.
4. Harmonic distortions. These are distortions in power due to other loads within the blood center that generate harmonics. In this case, both voltage and current harmonics can be transmitted to the critical mission loads.
5. Unstable power, which is caused by voltage and frequency fluctuation in the incoming supply due to a weak network system or overloaded network system.

There are a number of different methods that can be adopted to overcome problems resulting from power contamination.

1. For power surges and sags, line conditioners can be used. A UPS is a better solution as it provides both line conditioning and uninterrupted power supply functions.

2. Lightning surges can be overcome by provision of a surge diverter at the main switchboard.

3. Harmonic distortions can be handled in various ways, including passive filters, active filters, phase-shift transformers, etc. The appropriate solution depends on the nature of the harmonics.

4. Standby generators plus UPS to critical mission loads are another method of protecting against problems associated with power contamination. It is not possible to predict the potential problems that can be caused by power supply contamination. The best way to tackle this issue is to wait until the problem emerges and the underlying causes are identified. To permit solving problems caused by power contamination, it is crucial that spare circuits are available at the main switchboard and submain distribution boards so that surge diverters, UPS, line conditioners, filters, etc. can be added after the loads are connected.

*Uninterrupted Power Supply (UPS)*

For any equipment that may be damaged or any process that needs to be aborted in case of power failure, UPS should be considered. Much of the equipment comes with built-in battery power. However, if UPS is required, it is recommended that localized UPS be provided on an “as-required basis”. “Off-the-shelf” UPS units are recommended, as the replacement of a damaged unit will be more readily available.

*Power Distribution*

A compartmentalized main switchboard is recommended to be used (in order that failure of one circuit will not affect the rest of the main switchboard). Power distribution should be separated into different zones. The laboratories and process facilities should be separately zoned so that the operation will not be affected by the other non-critical areas. The distribution boards should be located with easy access and space for maintenance. The boards should be lockable for security purposes. Electric breaker panel should be clearly labeled and installed in separate closet. All electrical equipment must be grounded.

*General Power*

General power should be provided generously (a minimum of one double or two single outlets to each bench work position) General outlets should be color-coded to indicate the source of power supply to avoid unnecessary overloading of the generator or UPS systems. All outlets should be of the same type (round pins, square pins, etc.) throughout the facility. All outlets should be labelled with the circuit number and distribution board name for easy maintenance. Outlets in the laboratories should be controlled by an emergency stop push button. All outlets for the laboratory will be cut off when the emergency button is actuated. All power outlets for donor-connected equipment should be provided with RCDs (or earth leakage protection). Detailed architectural layouts and the Schedule of Equipment should be consulted to ensure that the appropriate type and number of power outlets are located to suite equipment requirements. Additional outlet should be provided to allow flexibility in the introduction of new equipment.

*General Lighting*

An efficient lighting method should be adopted. A fluorescent/Led lighting system is preferred over discharge lamp applications. Maximize the use of natural light in offices and laboratory areas. The lighting level should be designed to local standards, but a minimum of 320 lux in offices and 500 lux in Testing Laboratories will be required. In any areas where fine or precision work is carried out, local task lighting up to 700 lux may be used. Proper security lights should be provided around the premises and along the pathway to the car park. The car park should be properly lit for the security of the shift operation staff.

*Emergency Lighting*

An emergency and exit-sign lighting system should be provided at all entrance/exit doors of the premises as required by local building regulations. Battery-backed, self-contained light fittings are recommended. A central computer that monitors the wiring system should be installed to ensure simple, effective ongoing maintenance.

*Data and Voice System*

The available data and voice transmission system in the region should be checked with the local telecommunication service provider. Alternate connection from two feeds, if available, is recommended. A copper and fiber optic backbone structure should be provided throughout the premises. A PABX with adequate incoming lines and outgoing extensions should be provided for the whole premises. Structured cabling system utilizing UTP Category 5E cables should be provided to all voice and data outlets.

*Alarm System for Blood Storage Rooms and Equipment*

All cool rooms, freezer rooms and refrigerator and freezer cabinets should have alarms that are activated if the temperature moves beyond the specified range, or the failure of refrigeration equipment. All alarms should be provided with UPS supply so that they continue to operate during a power black-out situation, and during switch-overs between main and standby power supply. For cool rooms and freezer rooms, each refrigeration system should be provided with an internal fault detection system with external alarm connections, so that failure will initiate change over to standby power, and an alarm raised at the front end. Internal fault detection shall include high compressor head pressure, refrigerant flow, failure to respond to call to start, and power failure. Cool rooms and freezer rooms shall also be provided with temperature sensors as back up alarms. Each refrigerator and freezer cabinet should have internal fault detection with external connections. The internal fault system will detect power failure, refrigeration plant failure and temperature rise. The central alarm system should be provided with front end devices which show the set points for each piece of equipment being monitored, location of this equipment and alarms generated by this equipment. The central alarm system shall be powered by both normal and standby power supply via a UPS system to ensure continuous power during power failure periods. Audible alarms should be provided to all rooms and equipment being monitored. Audible and digital alarms should also be provided in the facility manager’s office and in the inventory and distribution office, if this department is staffed on a 24 hours basis. Where a BMS is provided, the central alarm system should be connected to an auto dial or similar software package, so that the alarm message can be sent to the facility manager and selected staff via mobile telephone or pager.

*Fire Protection System*

Depending on the configuration of the premises, a fire hydrant, hose reel, automatic sprinkler, portable fire extinguishers, and automatic fire detection systems may be required. Users should advise the design engineer of any areas where automatic sprinklers are incompatible, with activities being carried out in specific spaces and alternative fire protection systems designed. To ensure the effectiveness of the fire hydrant, hose reel and automatic sprinkler system, the reliability of the water supply should be checked. Alternative water sources such as storage tanks may be required. The pressure and flow information of the street water mains need to be identified. End users should advise engineers where sprinklers are inappropriate.

*Hydraulic System*

The reliability and availability of water supply and sewage and storm water drain facility should be checked, as should the quality of the water supply, to see if special filtration is required. The water quality required for all equipment should be verified, and if required, filtration or water treatment should be provided. A centralized reverse-osmosis filtration plant should be provided to ensure piped clean water to laboratories and blood processing areas. Special attention should be paid to the commissioning of the system, particularly regarding the plasticizing effect on the water.

*Vertical Transportation*

 If the premises are multistoried, a goods lift (elevator) is to be provided for delivery of goods and chemicals to the laboratories on the top floor. The size of the lift car and lift doors should be adequate to allow the movement of all pieces of equipment in the center. The design engineer should consult the Schedule of Equipment to determine the critical dimensions.

A dumb waiters or hoist can be used for the transport of blood and blood products.

A passenger lift (elevator) may be required depending on the local practice. An electro-hydraulic lift (elevator) can be considered for buildings up to three levels.

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