

Design Guidelines for Blood Centres



World Health
Organization

Western Pacific Region

Design Guidelines for Blood Centres



**World Health
Organization**

Western Pacific Region

WHO Library Cataloguing in Publication Data

Design Guidelines for Blood Centres

1. Blood transfusion. 2. Facility design and construction – standards.

ISBN 978 92 9061 319 0 (NLM classification: WB356)

© World Health Organization 2010

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland

(tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int). For WHO Western Pacific

Regional Publications, request for permission to reproduce should be addressed to the Publications Office, World Health Organization, Regional Office for the Western Pacific, P.O. Box 2932, 1000, Manila, Philippines, Fax. No. (632) 521-1036, email: publications@wpro.who.int

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

CONTENTS

- 1. **Introduction**1
 - Notes on the contents of the design guidelines

- 2. **Functional Brief**7
 - 2.1 Role and objective of the Blood Centre7
 - 2.2 Planning Issues
 - Growth and Change7
 - Risk Management7
 - Blood Flow9
 - Access and Location9
 - Hours of Operation9
 - Disabled Access9
 - Registration and Documentation9
 - Biosafety 11
 - Irradiation Facilities 11
 - Blood Disposal 11
 - Staff Amenities 11
 - Occupational Health and Safety 12
 - Education and Training 12
 - Security 12
 - Stores 12
 - Vehicle Parking 13
 - Engineering Services 13
 - Building Automation Systems (BAS) 13
 - Waste Management and Disposal 13
 - Dangerous Goods 13

 - 2.3 Departmental Objectives and Policies 14
 - 2.3.1 Blood Collection Facilities 14
 - Mobile Blood Collection Units and Vehicles 14
 - Demountable Collection Facilities 14
 - Static Collection Facilities 16
 - 2.3.2 Processing 23
 - 2.3.3 Inventory and Distribution 34
 - 2.3.4 Laboratories 42
 - 2.3.5 Quality Management 63
 - 2.3.6 Administration and Management 65
 - 2.3.7 Engineering Department 76

3. Design Brief	83
3.1 Facility Planning and Design	
– General Considerations.....	83
3.2 Site Selection.....	83
3.3 Good Manufacturing Practice (GMP).....	84
3.4 Building Elements.....	84
3.5 Engineering Services	88
Annex A	96
Reference Documents	96
Annex B	97
Useful Websites	97
Annex C	98
Role of the Facility Manager	98
Maintenance	99
Annex D	102
Glossary	102
Annex E	103
Abbreviations	103
Annex F	104
Acknowledgements.....	104

1 Introduction

Maintaining a supply of safe blood and blood products has become a national priority in many countries. Achieving this aim requires the development and implementation of a national policy and the development of guidelines to govern blood transfusion processes. There are a number of guidelines that spell out how quality and safety can be achieved.

These guidelines were prepared to assist countries in developing appropriate, purpose-built facilities for blood services. They may be used to guide the design of new buildings, to direct the renovation of existing facilities or even to improve work patterns by considering the layout in established facilities. Even if a new facility is not to be built, careful thought concerning the design and layout of an existing facility is essential for safe and efficient function. These guidelines are flexible. They can be adapted by countries with centralized services and by countries with multiple small facilities. Furthermore, buildings do not have to encompass every feature listed in these guidelines in order to be effective.

A safe blood supply depends on several important principles that have been set out by WHO in the Aide-Mémoire for National Blood Programmes: Blood Safety. The key elements are:

- establishment of a blood transfusion service;
- collection of blood from only voluntary, non-remunerated, low-risk blood donors;
- screening of all donated blood for transfusion-transmissible infectious agents; and
- reduction in unnecessary transfusions through the effective clinical use of blood.

Implementation of a quality management system covering all areas of the blood transfusion service is essential. Key elements—organizational management, standards, documentation, training and assessment—are outlined in the WHO Aide-Mémoire for National Blood Programmes: “Quality Systems for Blood Safety”.

Intent of the design guidelines

The Design Guidelines for Blood Centres was prepared by the WHO Regional Office for the Western Pacific. The need for such a document was identified at the Workshop on Nationally Coordinated Blood Transfusion Services, organized by WHO and held in Melbourne, Australia, 9–13 December 2002.

This document will serve as a tool for authorities responsible for developing buildings to house blood transfusion services. It will assist national blood transfusion services (BTS) or ministries of health in determining the likely size and necessary content of blood transfusion facilities and how these facilities might operate. It will also assist these authorities in developing an appropriate design brief with their building design teams.

These guidelines do not set out detailed and specific designs for blood centres. Each facility should be designed as a specific response to unique local conditions. Rather, the guidelines expound on the fundamental principles that should guide the development of detailed and specific designs when used by the BTS and their consultant design team. They should be read and used in conjunction with relevant national and local standards and applicable guidelines.

Government and BTS policies regarding the provision of a safe blood supply must be taken into consideration. It is emphasized that facilities are part of the BTS, but facilities alone do not create a BTS or a safe and sufficient blood supply.

Blood Services Models

No single blood services model is appropriate in all situations or locations. Rather, there are a range of models that vary from centralized to decentralized. The determination of what is the appropriate blood service model for a particular country, state or province must take into account a number of considerations including the existing blood service infrastructure, transport infrastructure and the availability of skilled and trained staff.

Centralized blood services model

In recent years, many developed countries have adopted a highly centralized blood services model with a national management structure and policies. A centralized blood centre (Processing, Testing, Inventory and Distribution) supports a large number of collection centres distributed across the area serviced. Where logistics permit, centralization of processing and testing facilities has operational efficiencies, such as the use of complex and expensive equipment, staff training and quality management programmes to deliver consistently high-quality products for patients.

Decentralized blood services model

Other countries have maintained a highly decentralized model with each collection centre supported by a Processing, Testing, Inventory and Distribution facility.

Some countries or regions have developed a hybrid of these two models, with some degree of harmonization of practice and centralization of post-collection activities. These guidelines have been written for both the newer centralized models and the more traditional decentralized ones.

Co-location of a small blood centre with a hospital

For small or isolated communities, it may be appropriate to co-locate the blood centre with a hospital. This arrangement, if well managed, permits the sharing of buildings, skilled staff and equipment.

The collection facility

Although the centre is co-located with a hospital, the donors are not patients. For social or cultural reasons, they may be reluctant to attend a donation centre in the hospital. It is therefore recommended that the collection facility should have its own address, signage and front door— separate from other hospital entries.

Processing and testing

Blood donation, processing and testing can be carried out in separate facilities at the hospital or within the hospital pathology department, but only if activities are clearly separated and the security of donated blood can be ensured. Integrating the processing and testing within the pathology department may allow for more efficient and flexible staff and equipment utilization. In small or isolated communities, it may also enhance community participation, and allow rapid turn-around time from donation to transfusion of blood.

Scope of the Guidelines

For small or isolated communities, it may be appropriate to co-locate the blood centre with a hospital. This arrangement, if well managed, permits the sharing of buildings, skilled staff and equipment.

The collection facility

Although the centre is co-located with a hospital, the donors are not patients. For social or cultural reasons, they may be reluctant to attend a donation centre in the hospital. It is therefore recommended that the collection facility should have its own address, signage and front door—separate from other hospital entries.

Processing and testing

Blood donation, processing and testing can be carried out in separate facilities at the hospital or within the hospital pathology department, but only if activities are clearly separated and the security of donated blood can be ensured. Integrating the processing and testing within the pathology department may allow for more efficient and flexible staff and equipment utilization. In small or isolated communities, it may also enhance community participation, and allow rapid turn-around time from donation to transfusion of blood.

Standards

Reference should be made to applicable national and local standards. Examples are included in the annex A. Equivalent standards from the International Organization for Standardization (ISO) may also be useful.

Notes on the contents of the design guidelines

The design guidelines are divided into two sections: (1) functional brief, including schedules of spaces, and (2) design brief.

The schedules of spaces list all the spaces in the facility, while the functional brief explains the relationship between units and departments and between spaces within these units and departments. Planning must ensure that all the scheduled spaces agree with the specified size and that departments and 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. This may require the production of wall elevations as well as plans of many critical spaces.

Functional brief and schedules of spaces

The functional brief describes the role and function of a blood centre 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 each of the average workloads (600, 200 and 100 units/day). Where daily workloads vary by more than 20%, the area of some spaces may have to be increased to handle the increased workload.

These schedules identify the required area for each room or space within each unit or department 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 metres (m²).

All areas are measured to the centre line of the walls enclosing the room or space.

These walls are assumed to be a nominal 100 millimetres (mm) thick.

These schedules are a guideline only and should be modified or adjusted to suit the specific requirements of each individual blood centre.

Design brief

The design brief sets 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

These guidelines do not include equipment schedules because equipment will vary greatly from centre to centre, depending on the specific processes and tests carried out within the centre. These processes and tests will change over time as the centre changes or modifies the processes and services it carries out. Furthermore, new equipment is constantly being developed either to carry out existing activities more efficiently, accurately or more cheaply or to carry out new processes or tests.

Even though equipment schedules are not included in the brief, 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; and,
- the equipment budget is adequate.

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

- equipment name, make and model number;
- critical dimensions;
- weight;
- power requirements;
- services requirements, including gas, water supply and drainage;
- heat output; and,
- location (floor, trolley or bench mounted).

2 Functional brief

2.1 Blood Centre

The blood centre is the location for the collection, receipt, processing, testing, storing and distribution of blood. It also usually houses the administration of the BTS or is closely associated with it. The blood centre may accommodate a static blood collection facility while also coordinating mobile and demountable collection facilities. Additional national or regional specialist laboratory services and research activities may also be provided from the facility.

2.2 Planning issues

Growth and change

Blood centres are not static over time. They change and grow. Change is driven by a number of factors including the introduction of new technologies, equipment and processes, new clinical practices in the use of blood and the improved education and training of staff.

Blood centres grow to absorb change and to provide increased capacity required to service population increases. When the centre is located on a large parcel of land, growth may occur simply by expanding the centre. When the site is small and the centre is multi-storeyed, growth is more difficult. Some flexibility can be achieved by locating offices (soft or easily re-locatable accommodation) adjacent to areas such as the laboratories that are likely to grow. In extreme cases, some of the offices may be relocated off-site.

Risk Management

The blood centre is responsible for the processing, testing and storage of blood in the national or provincial BTS. If the facility is centralized, any failure in the processing, testing and storage of blood, or of the building that house these activities, may have a highly adverse impact on the BTS.

The blood centre building, and particularly its engineering services, should be designed with close consideration of likely risks and how best these can be managed. This will often result in a degree of duplication in some of the engineering equipment.

As part of the organization's overall risk management strategy, an action plan should be formulated and implemented in the event of a processing, testing, building or services failure to ensure that verified blood is available as required.

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 centre 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 centre 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 in a critical disruption to the supply of blood in the health system. As part of the centres 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. (Refer to Section 3.5 Engineering Services for cool room design to manage the risk of refrigeration failure).

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 centre should permit the movement of blood in one direction through the centre. 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.

Access and Location

The blood centre is the hub for the collection, storage and distribution of blood and blood products. It must be accessible to the staff, donors, the delivery of supplies and equipment and the dispatch of blood. To carry out these roles effectively, the facility must be located close to major public transport routes and population centres. Although road access is of primary importance, good road access from the facility to major rail nodes and/or airports will also be important for facilities covering large geographic areas.

Hours of operation

The Inventory and Distribution areas of a blood centre generally 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 centre usually operate during normal business hours, although collection centres may operate out of business hours to maximize donor access. The design of the centre 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 centre.

Disabled access

The blood centre should be accessible to staff and donors with disabilities. The health sector should lead the way in providing wheelchair access in buildings where differences in levels of flooring occur. Doors, corridors and toilet compartments should also be built to accommodate persons in wheelchairs.

Blood and sample registration

Real-time control of all blood and blood sample movement into and out of the centre 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 centre should pass through a central reception and/or registration point. Some blood centres have a separate registration point in the laboratories for samples referred from elsewhere for testing at the centre. If this is proposed, a risk assessment should be carried out to determine if maintaining two registration points in the centre (central registration usually in Processing and a

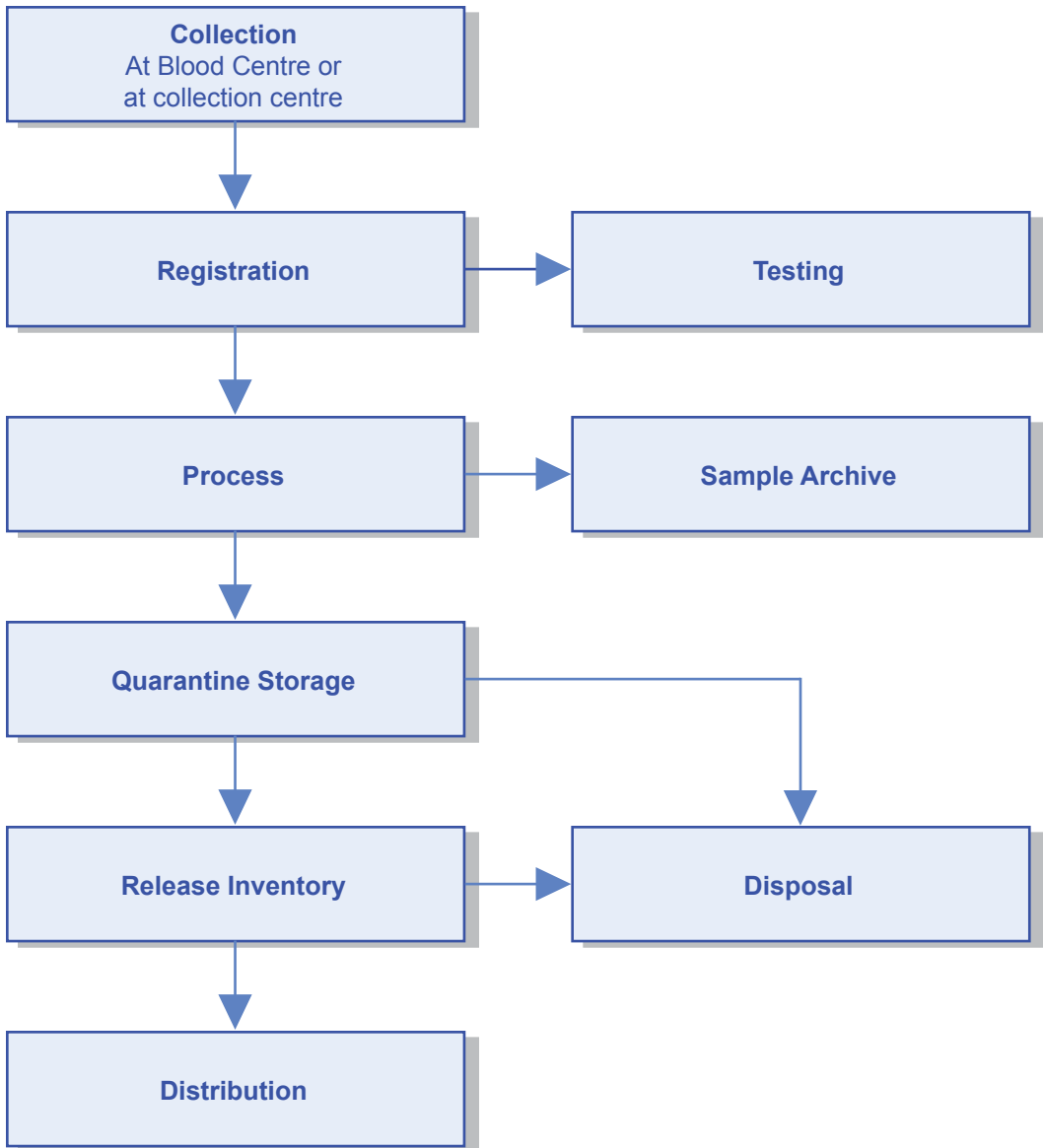


Figure 1. Blood flow.

sample registration in the Testing Laboratories) poses any threat to accurate and total documentation of all blood units and samples.

Similarly, all blood distributed from the centre should be documented at a central dispatch registration point. All blood disposed on site or sent off site for disposal should be documented at a central disposal registration point.

Biosafety

Biosafety policies must be in place for protection of donors, 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.

Irradiation facilities

Some blood centres may require irradiation of blood and blood products. In such centres irradiation facilities must be designed according to local building and radiation standards and regulations. Special attention must be paid to enclosure of the irradiation equipment and the management of any waste materials generated. Where local standards and regulations do not exist, facilities should be designed in accordance with international standards (refer to Appendix A: Reference Documents).

Blood irradiation equipment is very heavy. The structural engineer should check to ensure that the structure is adequate to support the irradiator.

Blood disposal

The blood centre should have policies for the safe disposal of blood, blood products or blood-contaminated disposable equipment. Items requiring disposal include contaminated blood samples from the laboratory, contaminated blood held in quarantine storage, and blood that has passed its use-by-date. This blood should either be treated on site by heat sterilization, incineration and chemical treatment or be securely stored for collection and disposal off site by a specialist contractor.

Staff amenities

Staff toilets and wash basins should be easily accessible from all work areas. Locker rooms and staff lounges or tea rooms may be centralized within the blood centre or decentralized within individual units, depending on the size of the facility. 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 centre should be designed to ensure the health and safety of staff, visitors and donors. 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.

Education and training

A wide range of education and training services may be carried out at the blood centre. In addition, education and training programmes may be planned and organized at the blood centre and be delivered at hospitals, clinics or in the wider community.

Education and training services may be provided to staff (medical, scientific and nursing) at hospitals and clinics and to donors or potential donors. Research may also be carried out at the facility.

Security

A physically secure environment must be provided at the facility for staff and donors. Easy public access is essential for activities such as for blood donation activities. 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.

Where blood centres have on-site security staff, adequate space and facilities must be provided for these staff.

Stores

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

Donor record storage requirements will vary greatly according to local regulations. Typically current records (two to five years) will be held on site. Archival donor record storage of up to 20 years will also be required. These archival records may be stored off site.

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. Additional parking spaces should be provided for donor cars and motorcycles, BTS buses, vans, taxis, cars and motorcycles used for donor transport. 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.

Computers

Computers, wherever possible, should be connected internally to a LAN. A network server of the appropriate manufacture commensurate with the local systems should be provided. Computer security is essential to protect confidential and critical data.

Waste management and disposal

Blood centres generate a wide range of waste material, including general waste, trade waste (i.e. chemical waste being discharged into the sewer), biological waste and waste radiation materials. The blood centre must review all its processes to identify the type and amount of each type of waste and develop policies and protocols for its handling, storage and disposal. Disposal of some waste materials may be carried out on site while other materials may be collected and disposed of off site by specialist contractors in accordance with local waste disposal regulations.

Dangerous goods

Chemicals stored within laboratory areas should be less than the maximum allowable by the local building codes and regulations so that the laboratory need not be classified as a “hazardous area”; otherwise, very stringent building and fire protection requirements will be imposed on the laboratory.

2.3 Department objectives and policies

2.3.1 Blood collection facilities

Blood may be collected in a number of different types of collection facilities including:

- mobile collection units or vehicles;
- demountable collection centres;
- stand-alone static collection centres; and,
- static collection facility located in a blood centre.

The decision as to which type of collection centre or mix of types will depend on local conditions including existing and projected blood centres and donor location and access.

Mobile collection units or vehicles

Mobile collection units are usually buses or coaches that are driven to locations accessible to donors. These types of units are not covered in this document. If a BTS is considering the introduction of mobile collection units, it should confer with blood services already using this type of collection facility.

Demountable collection centres

Concept

In many towns, villages, rural areas and islands, population numbers and densities are too small to support permanent static collection facilities. However, these areas may be home to over 70% of the national population in some countries and cannot be overlooked as a source of blood donations. In these locations, demountable collection centres may be appropriate.

All the equipment and furniture required for a demountable collection centre is transported in a truck that is usually based at the blood centre. The vehicle is driven to a temporary collection facility in an existing building, where the furniture and equipment are unloaded, and the facility set up for a number of days. When done, the furniture and equipment are packed back onto the vehicle, which then proceeds to its next destination or returns to the blood centre.

Where demountable units are used, care should be taken to ensure the best possible building environment is achieved. Non-blood centre buildings used as temporary collection centres should meet the same standards of building finishes as regular blood centre facilities.

Scope of services

- (1) Screen potential donors.
- (2) Collect appropriate donor information and administer donor health questionnaire
- (3) Collect blood from eligible donors.
- (4) Supervise donor recovery.
- (5) Check and store donated blood prior to dispatch to a testing and processing facility.

Workload

Workloads for mobile or demountable collection centres cannot be accurately determined without detailed knowledge of local conditions. Therefore, they will not be covered by these guidelines. The annual workload will be determined by the number of days that facilities are actually collecting blood. A significant but variable amount of time will be spent travelling between collection locations and setting up and dismantling the collection centres.

Hours of operation

Demountable collection centres are generally set up for one to four days in any one location. Hours of operation should be locally determined to ensure maximum donor convenience and access.

Functional content

Waiting area	Area for donors to wait prior to interview and donation
Interview	One or more dedicated space
Donation area	Space where a number of couches could be set up
Donor lounge	Post-donation lounge for donor recovery and observation by staff
Staff area	Staff lounge and tea room
Store	General storage for equipment and consumables
Blood storage	Space for refrigerated or insulated blood containers
Toilets	Toilets for staff and donors

Location

Demountable collection centres should be set up in a highly visible location with good public access. The building selected for a demountable facility should have an abundance of natural light, particularly in donor areas, and maximum open planning to improve staff observation of donors. Interview rooms should have visual and acoustic privacy. In all spaces where blood is handled or stored, materials and finishes should conform to relevant guidelines and regulations.

Connection to a power grid is highly desirable although power can be supplied by a mobile generator.

Building Fabric

The building selected for a demountable collection centre should have the following existing services: adequate power for all engineering services; washbasins accessible from all donor and blood handling areas; and toilets for donor and staff use.

In addition to existing services, the following should be provided:

- diesel powered stand-by generator with adequate power to run ventilation, air conditioning (if provided), selected lighting, all donor-connected equipment and refrigerated blood storage;
- colour-corrected lighting to donor areas;
- battery operated digital clocks in donor areas;
- refrigerated blood cabinet; and
- RCD protection to equipment connected to donors.

Static collection centres

Concept

Static blood collection centres are facilities for blood donation in fixed or permanent locations. They are the first point of contact between the donor and the BTS. They may be stand-alone facilities or located within a blood centre.

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 a testing and processing facility.
- (5) Manage donor results.

Additional services

Donor recruitment and education activities may be based at the facility or coordinated by its staff. Donor or patient apheresis may be carried out at the facility if this service is provided by the BTS.

Workload

A 12 couch facility should be able to collect a minimum of 18,000 whole blood donations annually (or a minimum average of 72 donations daily). An 8 couch facility should be able to collect a minimum of 12,000 whole blood donations annually (or a minimum average of 50 donations daily).

Apheresis collections take twice as long as whole blood collections. Where apheresis collections are carried out daily, annual numbers of donations should be adjusted based on the ratio of apheresis to whole blood collections.

Hours of operation

Collection facilities should operate to facilitate the needs of donors. Hours of operation will vary from location to location. Typically, collection facilities will operate during shopping or office hours, but may open early on some mornings or remain open on some evenings to permit donation before or after work, shopping or school. Collection facilities may also be open on some weekends and public holidays.

Location

Static collection facilities should be set up to ensure maximum public access. Good public transport access and appropriate parking are essential. Typically, stand alone collection centers are located in large shopping malls, city facilities, major industrial complexes, religious institutions, universities or hospitals. In some circumstances it may be appropriate to locate collection facilities in purpose-built, stand-alone buildings. Clear signage should be used to identify the collection centre and provide directions to the donors.

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

A static collection centre facility should provide the following areas:

Waiting area	Operators should assess numbers. Numbers will vary according to local practices, e.g. if donors are accompanied by a family member, if work or community groups attend together.
Reception	Staff base for the management and direction of donors on arrival.
Donor Records	Directly accessible from Reception so that records can be retrieved on donor arrival.
Interview	Rooms for collection of confidential and medical information as well as counselling. Numbers will depend on expected daily workload.
Haemoglobin Screening	Area for testing blood haemoglobin levels of potential donors.
Donation area	Space for couches and adjacent consumables storage. Additional space required if apheresis is carried out, but this can be carried out in an area shared with other couches.
Checking/holding	Physical checking of collected units and donor samples prior to transport to laboratory or holding facility respectively.
Donor treatment	Space for donor treatment and recovery in case of an adverse reaction during or after donation.
Donor lounge Staff Area	Post-donation lounge for donor recovery and refreshment with accommodation for observation by staff. Multi-purpose staff lounge and tea room.
Offices	Facility manager and other administrative staff.
Meeting room	BTS meetings and training activities.
Store	Supplies for donor screening, haemoglobin testing, blood collection, etc.
Laundry	For linen and staff lab coats if required. Alternatively, external laundry service may be used. Where the collection centre is located in a blood centre, a central laundry may be provided in the housekeeping area.
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:

- $24^{\circ}\text{C} \pm 2^{\circ}\text{C}$ DB/ $50\%\text{RH} \pm 10\%$ in summer
- $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$ 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				
Static blood collection centre—8 couches				
Space	Area	No.	Total	Comments
Reception/Reception	9	1	9	
Donor toilet - male	3	1	3	
Donor toilet - female	3	1	3	
Waiting area	28	1	28	Accessible from Reception/Registration. Allow 1.5 m ² for each person waiting. Assume two persons waiting per couch. Review this figure against local practice.
Donor records	12	1	12	Check against local record storage regulations.
Interview room	7	3	21	
Examination Room	9	2	18	
Haemoglobin screening	7	1	7	
Collection area	72	1	72	Allow 9 m ² per couch.
Staff work base	6	1	6	For staff in collection area
Linen bay	2	1	2	Linen stored on trolley
Screening (post donation)	13	1	13	
Donor lounge	24	1	24	Allow 3 m ² per couch.
Pantry	8	1	8	Used for preparation of drinks and snacks for donors post donation.
Donor treatment	6	1	6	For donors experiencing post donation reactions
Store	12	1	12	May be reduced to 10 m ² if mobile shelving is available
Linen				
Office - centre manager	9	1	9	Check against local practice
Staff room	18	1	18	Serves as multipurpose room.
Meeting room	18	1	18	Used for meetings and training.
Cleaner	4	1	4	
Waste holding	6	1	6	
Circulation (30%)				
Notes:				
(1) Review local practice when determining the number of waiting spaces per couch.				
(2) Allow 10 m ² per apheresis couch where applicable. Apheresis collections generally take twice as long as whole blood collections. Where apheresis collections are used, number of collection couches should be reviewed.				
(3) Increase area of store by 8 m ² if apheresis collections are being carried out.				

Schedule of spaces
Static blood collection facility—12 couches

Space	Area	No.	Total	Comments
Reception/Reception	9	1	9	
Donor toilet - male	3	1	3	
Donor toilet - female	3	1	3	
Waiting area	36	1	36	Accessible from Reception/Registration. Allow 1.5 m ² for each person waiting. Assume two persons waiting per couch. Review this figure against local practice.
Donor records	16	1	16	Check against local record storage regulations.
Interview room	7	4	28	
Examination Room	9	2	18	
Haemoglobin screening	7	1	7	
Collection area	108	1	108	Allow 9 m ² per couch.
Staff work base	6	1	6	For staff in collection area
Linen bay	2	2	4	Linen stored on trolley
Screening (post donation)	13	1	13	
Donor lounge	36	1	36	Allow 3 m ² per couch.
Pantry	8	1	8	Used for preparation of drinks and snacks for donors post donation.
Donor treatment	6	1	6	For donors experiencing post donation reactions
Store	16	1	16	May be reduced to 12 m ² if mobile shelving is available
Office - centre manager	9	1	9	Check against local practice
Staff room	24	1	24	Serves as multipurpose room.
Meeting room	24	1	24	Used for meetings and training.
Cleaner	4	1	4	
Waste holding	6	1	6	
Circulation (30%)				

Notes:

- (1) Review local practice when determining the number of waiting spaces per couch.
- (2) Allow 10 m² per apheresis couch where applicable. An apheresis collection generally takes twice as long as whole blood collections. Where apheresis collections are used, number of collection couches should be reviewed.
- (3) Increase area of store by 8 m² if apheresis collections are being carried out.

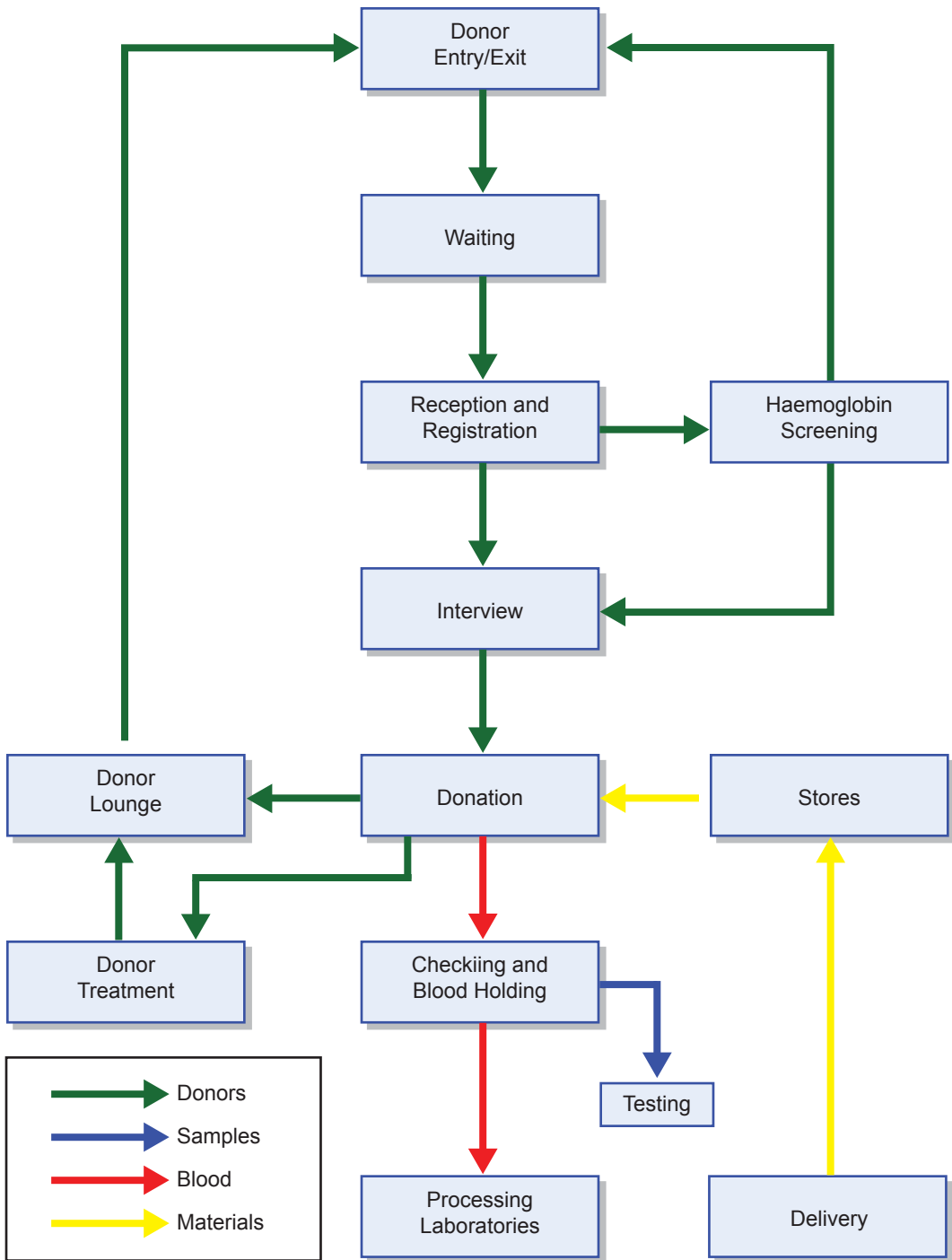


Figure 2. Static blood collection facility. - Functional relationship

Water supply

Washbasins with hot and cold water should be available in the checking area, donor treatment area and patient lounge. The donor lounge should also be furnished with beverage preparation equipment, as required.

2.3.2 Processing

Concept

The Processing Unit is responsible for the reception of all blood entering the blood centre, its processing and storage. The unit may be co-located with the Inventory and Distribution unit and the testing Laboratories or located on a separate site.

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.

Workload

The Processing unit should be designed to handle the specific workload of the blood centre. As the number of blood units requiring processing will fluctuate from day to day reflecting local collection practice, blood centre managers and operators will have to determine the maximum daily number of blood units requiring processing (which 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 the blood. Blood centres should determine their hours of operation to suit local conditions.

Location and relationship

The Processing unit should be located on the ground level with good access for delivery vehicles. If the central blood reception area is located within the unit, it should have good access to the laboratories through co-location or good transport access between the two sites.

It is recommended that the Processing unit may be co-located with the Inventory and Distribution unit and the testing Laboratories. If, however, they are located on different sites, there must be good transport connections between the two sites to permit the efficient movement of blood from processing to inventory and distribution.

Workflow

Blood reception

All blood units from collection facilities and referred blood samples from hospitals and clinics will be received at the central reception area. Blood reception and registration should follow the blood centre 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 often separated into blood components for transfusion. In some situations, plasma may also be sent to a specialist facility for further fractionation. Blood is usually separated into plasma, red cells and platelets. Additional activities including leucocyte filtration, cryopreservation and washing of cellular components, and pathogen inactivation may also be 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

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. Depending on the type of blood component prepared and complexity of the process, additional areas may be required (i.e. leucofiltration, blood irradiation, pathogen inactivation etc.)
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.
Offices	Process manager and process supervisors
Toilets	Separate male and female toilets

Waste management

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

Housekeeping

The unit should be cleaned in accordance with established blood centre 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 (refer to hours of operation above).

Additional spaces will be required if preparation processes include blood irradiation, leucocyte filtration, cryopreservation and washing of cellular components, 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 4°C cool rooms and walk-in -20°C freezers for large processing units, or freezer and refrigerator cabinets for smaller units, should be provided. Walk-in (20°C-24°C) 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.

Biosafety

Biohazard cabinets and hoods should be provided as required and positioned appropriately. The operation time of the hoods should be established so that the air pressure regime in the area can be established.

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 400 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

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. Where a proximity access card system is not available, keypad locks or key-operated locks with emergency exit hardware should be used throughout the unit.

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.

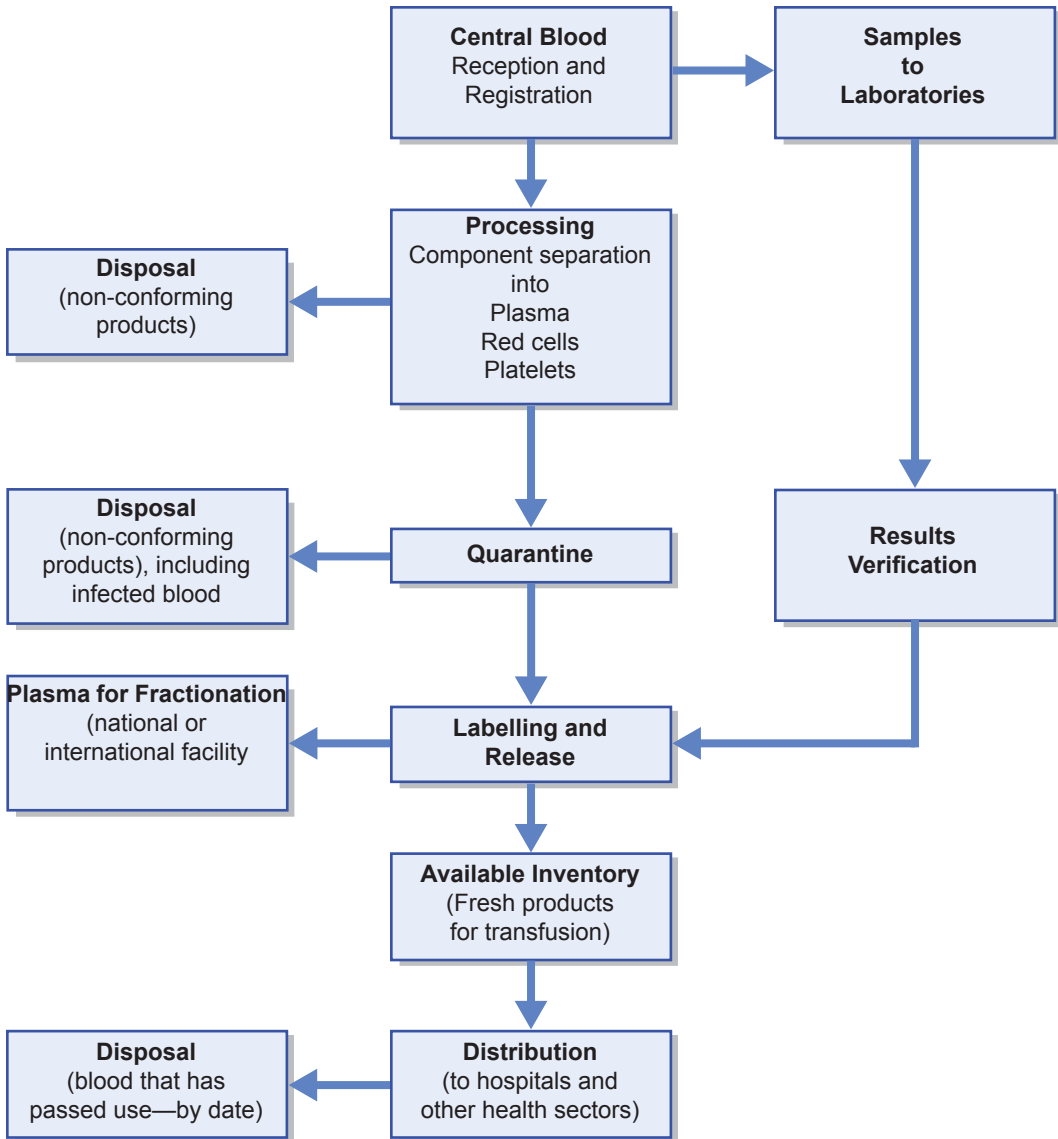


Figure 3. Processing and Distribution – functional relationships

Schedule of Spaces Processing—100 units/day centre				
Space	Area	No.	Total	Comments
Loading dock	8	1	8	Allow covered parking for two vehicles.
Blood and sample reception	12	1	12	
Document store	7	1	7	Check against local record storage regulations.
Store	9	1	9	
Handwash and gowning bay	6	1	6	At entry/exit to component preparation area
Component preparation	50	1	50	Refer notes below.
Plasma freezing area	10	1	10	Rapid plasma freezing
Quarantine refrigerated cabinets for red cells (4°C)	5	1	5	
Quarantine freezer cabinets for plasma (-30°C)	9	1	9	
Quarantine store for platelets (20°C-24°C)	4	1	4	Walk-in store with platelets stored in cabinets
Quarantine freezers	8	1	8	Freezer cabinets
Contaminated blood store	4	1	4	Blood for disposal stored in refrigerated cabinets
Verification and labelling	9	1	9	
Office - process manager	9	1	9	Adjust to local practice
Waste holding	4	1	4	
Staff tea room	9	1	9	
Staff toilet - female	3	1	3	1 WC pan, 1 washbasin
Staff toilet - male	3	1	3	1 WC pan, 1 washbasin
Refrigeration plant	12	1	12	Locate outside building close to cool rooms and freezers. Adjust to suit equipment and processes
Circulation (30%)				

Schedule of spaces Processing—200 units/day centre				
Space	Area	No.	Total	Comments
Loading dock	8	1	8	Allow covered parking for two vehicles.
Blood and sample reception	12	1	12	
Document store	9	1	9	Check against local record storage regulations.
Store	12	1	12	
Handwash and gowning bay	6	1	6	At entry/exit to component preparation area
Component preparation	80	1	80	Refer notes below.
Plasma freezing area	10	1	10	Rapid plasma freezing
Quarantine cool room for red cells (4°C)	7	1	7	Walk-in. Refer notes below
Quarantine freezer for plasma (-30°C)	14	1	14	Walk-in. Refer notes below
Quarantine store for platelets (20°C-24°C)	5	1	5	Walk-in store with platelets stored in cabinets
Quarantine freezers	8	1	8	Freezer cabinets
Contaminated blood store	4	1	4	Blood for disposal stored in refrigerated cabinets
Verification and labelling	12	1	12	
Office - process manager supervisor	12	1	12	Adjust to local practice
Waste holding	6	1	6	
Staff tea room	9	1	9	
Staff toilet - female	3	1	3	1 WC pan, 1 washbasin
Staff toilet - male	3	1	3	1 WC pan, 1 washbasin
Refrigeration plant	12	1	12	Locate outside building close to cool rooms and freezers. Adjust to suit equipment and processes
Circulation (30%)				

Schedule of spaces Processing—600 units/day centre				
Space	Area	No.	Total	Comments
Loading dock	15	1	15	Allow covered parking for two vehicles.
Blood and sample reception	16	1	16	
Document store	12	1	12	Check against local record storage regulations.
Store	12	1	12	
Handwash and gowning bay	6	1	6	At entry/exit to component preparation area
Component preparation	150	1	150	Refer notes below.
Plasma freezing area	13	1	13	Rapid plasma freezing
Quarantine cool room for red cells (4°C)	16	1	16	Walk-in. Refer notes below
Quarantine freezer for plasma (-30°C)	42	1	42	Walk-in. Refer notes below
Quarantine store for platelets (20°C-24°C)	6	1	6	Walk-in store with platelets stored in cabinets
Quarantine freezers	12	1	12	Freezer cabinets
Contaminated blood store	4	1	4	Blood for disposal stored in refrigerated cabinets
Verification and labelling	24	1	24	
Office - process manager	9	1	9	Adjust to local practice
Office - two process supervisors	13	1	13	Adjust to local practice
Waste holding	6	1	6	
Staff tea room	12	1	12	
Staff toilet - female	6	1	6	2 WC pans, 2 washbasins
Staff toilet - male	6	1	6	1 WC pan, 1 washbasin
Refrigeration plant	15	1	15	Locate outside building close to cool rooms and freezers. Adjust to suit equipment and processes
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 in the light of local practice and regulations and to accommodate new or additional equipment and processes.
- 2) The schedule is based on the unit operating from 09:00 to 18:00 hours. If the unit operates over a longer period areas may be reduced.
- 3) Additional specific spaces will be required if the unit is carrying out additional processes including:
 - blood irradiation
 - leucocyte filtration
 - cryopreservation and washing of cellular components
 - pathogen inactivation
- 4) If large volumes of plasma products are being held prior to dispatch to an external fractionation facility, provide additional freezer holding.
- 5) 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.
- 6) Allow a minimum of 600mm between refrigerated centrifuges and between refrigerated centrifuges and walls to permit heat dissipation.
- 7) Staff facilities including toilets and tea rooms may be provided within the unit or centralized within the blood centre depending on BTS policy.

2.3.3 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. It is recommended that the Inventory and Distribution unit be co-located with and adjacent to, but separate from the Processing unit. If this is not possible, it can be located on a separate site. 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, fax, 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. Safe, rapid access for staff to issue blood when required is also essential.

Location and relationship

The Inventory and Distribution unit should be located on the ground level with good access for dispatch vehicles. It may be co-located adjacent to the processing unit or on a separate site. If however, they are located on different sites, there must be good transport connections between the two sites to permit the efficient movement of blood from processing to distribution.

Workflow

Labelled (verified) blood products are received from the Processing unit and held in temperature-controlled release inventory stores.

Upon request, either by telephone, facsimile 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 centre’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 centre 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 centre	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.
Offices	Dispatch manager and dispatch supervisors.
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:

- $24^{\circ}\text{C} \pm 2^{\circ}\text{C DB/ } 50\% \text{ RH} \pm 10\%$ in summer
- $20^{\circ}\text{C} \pm 2^{\circ}\text{C DB/ } 40\% \text{ RH}$ minimum in winter

Cool rooms and freezers

Walk-in 4°C cool rooms and walk-in -25°C freezers for large Inventory and Distribution units, or freezer and refrigerator cabinets for smaller units, will be provided. Walk-in 20°C – 24°C controlled environment rooms for platelet storage will be provided. Alternatively, 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 centre.

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 400 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. 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 be pre-filtered prior to recirculation in the unit.

Schedule of spaces
Inventory and distribution – 100 units/day

Note:

Note:

Space	Area	No.	Total	Comments
Loading dock	8	1	8	Allow covered parking for one vehicle.
Release refrigerated cabinets for red cells and fractionated plasma products	10	1	10	
Release freezer cabinets for plasma (-30°C)	10	1	10	
Release store for platelets (20°C-24°C)	7	1	7	Platelets stored in cabinets.
Distribution work area	12	1	12	
Store	6	1	6	Storage of cleaned refrigerated transport boxes.
Communication room	8	1	8	Receive requests for blood and blood products from hospitals. Manage dispatch of blood and blood products to hospitals.
Office - distribution manager or supervisor	9	1	9	Adjust to local practice
Dispatch waiting	6	1	6	For couriers collecting blood and blood products.
Staff tea room	8	1	8	
Staff toilet - female	3	1	3	1 WC pan, 1 washbasin
Staff toilet - male	3	1	3	1 WC pan, 1 washbasin, 1 urinal
Refrigeration plant	8	1	8	Locate outside building close to cool rooms and freezers.
Circulation (30%)				

**Schedule of spaces
Inventory and distribution – 200 units/day**

Space	Area	No.	Total	Comments
Loading dock	8	1	8	Allow covered parking for one vehicle.
Release refrigerated cabinets for red cells and fractionated plasma products	16	1	16	
Release freezer cabinets for plasma (-30°C)	16	1	16	
Release store for platelets (20°C-24°C)	6	1	6	Platelets stored in cabinets.
Distribution work area	16	1	16	
Store	9	1	9	Storage of cleaned refrigerated transport boxes.
Communication room	8	1	8	Receive requests for blood and blood products from hospitals. Manage dispatch of blood and blood products to hospitals.
Office - distribution manager or supervisor	9	1	9	Adjust to local practice
Dispatch waiting	6	1	6	For couriers collecting blood and blood products.
Staff tea room	8	1	8	
Staff toilet - female	3	1	3	1 WC pan, 1 washbasin
Staff toilet - male	3	1	3	1 WC pan, 1 washbasin1
Refrigeration plant	8	1	8	Locate outside building close to cool rooms and freezers.
Circulation (30%)				

Schedule of spaces Inventory and distribution – 600 units/day				
Space	Area	No.	Total	Comments
Loading dock	16	1	16	Allow covered parking for two vehicles for couriers to collect blood
Reception/waiting area	42	1	42	Walk-in. Refer to notes below
Release cool room for red cells and fractionated plasma products (4°C)	42	1	42	Walk-in. Refer to notes below
Release freezer for plasma (-30°C)	9	1	9	Platelets stored in cabinets.
Release store for platelets (20°C-24°C)	8	1	8	Freezer cabinets
Release freezers	36	1	36	
Distribution work area	13	1	13	Storage of cleaned refrigerated transport boxes.
Store	10	1	10	Receive requests for blood and blood products from hospitals. Manage dispatch of blood and blood products to hospitals.
Communication room	9	1	9	Adjust to local practice
Office - distribution manager	13	1	13	Adjust to local practice
Office - two distribution supervisors	6	1	6	For couriers collecting blood and blood products.
Dispatch waiting	12	1	12	
Staff tea room	6	1	6	2 WC pans, 2 washbasins
Staff toilet - female	6	1	6	1 WC pan, 1 urinal, 2 washbasins
Staff toilet - male	15	1	15	Locate outside building close to cool rooms and freezers.
Refrigeration plant				
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 in the light of local practice and regulations and 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) If plasma is being held prior to dispatch to an external fractionation facility, provide additional freezer holding and packing spaces.
- 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 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 centre, depending on BTS policy.
- 6) Separate cabinets may be required if the temperature requirements or distribution process for the red cells and plasma products differ.
- 7) Blood service should check the exact storage conditions that have been validated and recommended by the plasma derivative manufacturer. In the event that these differ, then a different refrigerator may be used.

2.3.4 Laboratories

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, pre-transfusion testing, platelet serology, and tissue typing. Some blood centres may also include haematopoietic stem cell processing and cord blood processing/storage activities; however, these will not be included in the scope of these guidelines.

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, haemoglobin content, haemolysis, sterility testing, etc.

Testing for patients

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

- Red cell serology and reference laboratory activities: blood group confirmation, identify red cell antibodies, prepare reagents including red cell panels, etc.
- Pre-transfusion testing: ABO/Rh grouping for donor and patient, antibody screening, compatibility testing, investigation of transfusion reactions, etc.
- Platelet and granulocyte immunology: detection and identification of platelet antibodies, platelet antigen typing, etc.
- Tissue typing: HLA antigen typing, pre-transplant compatibility testing.

Tissue typing may be carried out in some all blood centres. The activities carried out in the tissue typing laboratory, if present; vary from simply supporting the screening of blood donors and patient samples as part of the platelet refractoriness investigations to full laboratories that support organ and bone marrow transplant programmes. The scope of service must be clearly defined to permit planning of these laboratories. If organ and bone marrow transplant programs' are to be supported, the laboratories may require accreditation from organizations such as the American Society for Histocompatibility and Immunogenetics (ASHI) or the Australasian and South East Asian Tissue Typing Association (ASEATTA).

Additional services

Research and development

This unit may carry out any of the following activities:

- basic research;
- product-related research and development of blood component for research, further manufacture and therapeutic use; and,
- clinical research.

Immunology services

The immunology unit may provide a diverse range of services including testing of referred samples for:

- granulocyte and platelet immunological investigations from blood donors or patients, including investigation of transfusion reactions;
- pre-transplant compatibility testing.

The unit may be involved in service to a bone marrow registry where this service is provided.

Nucleic acid testing (NAT)

Where nucleic acid testing is carried out in the testing laboratories, this is now a fully automated process using a fully enclosed processor. The use of this equipment requires trained staff and a dedicated room.

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.

Library

The library provides staff access to standard blood science texts and current journals. Internet access should be provided if possible. The library should not be located within the laboratory area, but should be readily accessible to laboratory staff.

Workload

The testing laboratories will be required to screen samples of all donated blood within their service area. They may also be required to carry out additional tests on referred samples from hospitals and clinics.

Functional content

Refer to the Schedules of Spaces.

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 centre 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 centre policy.

Housekeeping

The unit should be cleaned in accordance with established blood centre 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 selection 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:

- 24°C ± 2°C DB/ 50% RH ± 10% in summer;
- 20°C ± 2°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. If BSL3 laboratories are required, they should be maintained at differential air pressure via air locks for containment purpose. A separate air handling unit with high-efficiency particulate air (HEPA) filters should be provided to the BSL3 laboratories.

Cool rooms and freezers

Walk-in 4°C cool rooms and walk-in -25°C freezers or freezer and refrigerator cabinets will be provided for products and/or reagents and sample storage. 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, in the Inventory and Distribution unit if staffed 24/7 and 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 centre. Refer page 5) 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.

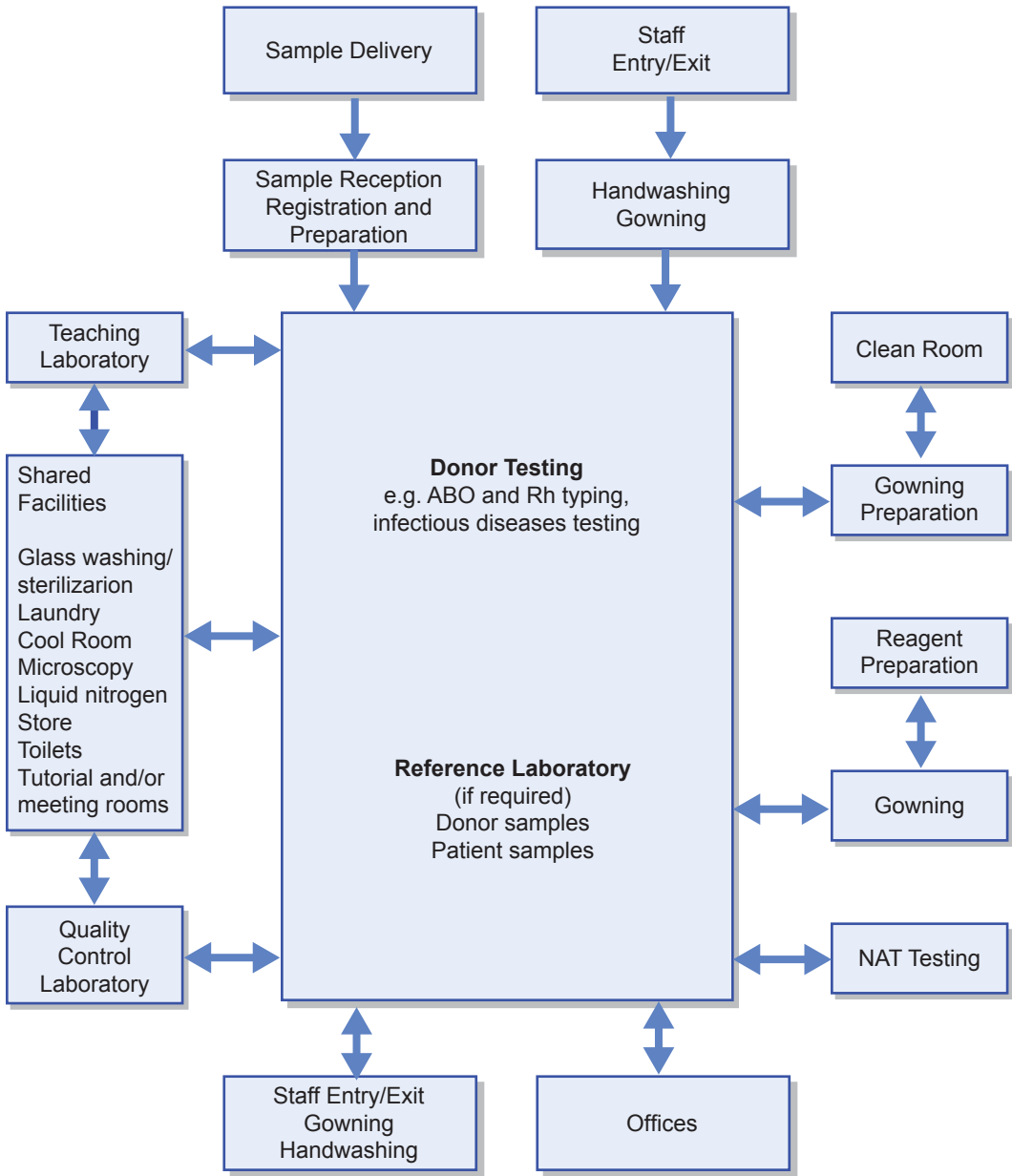


Figure 5: Laboratories planning relationships

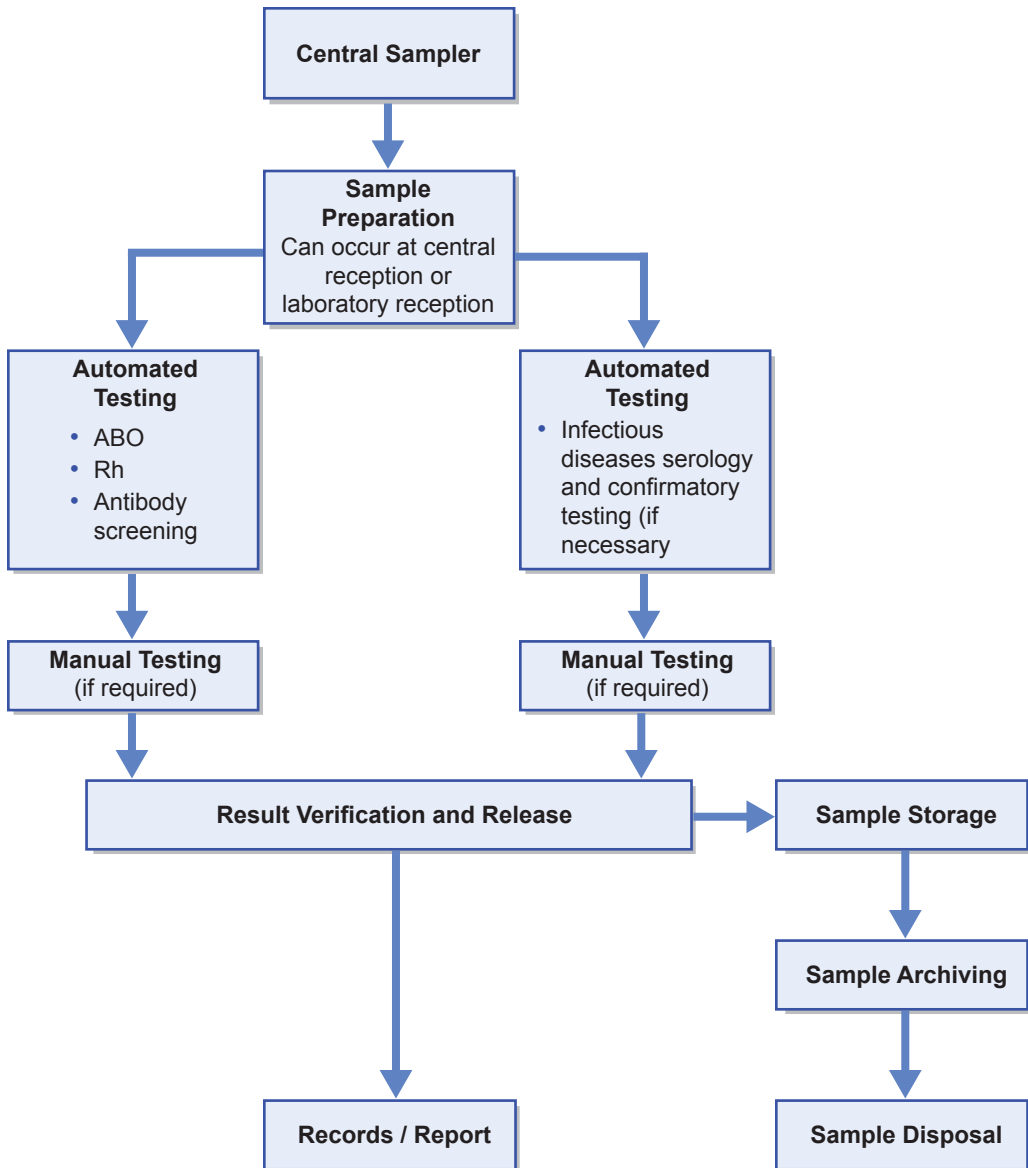


Figure 6. Laboratory process flow: donor testing

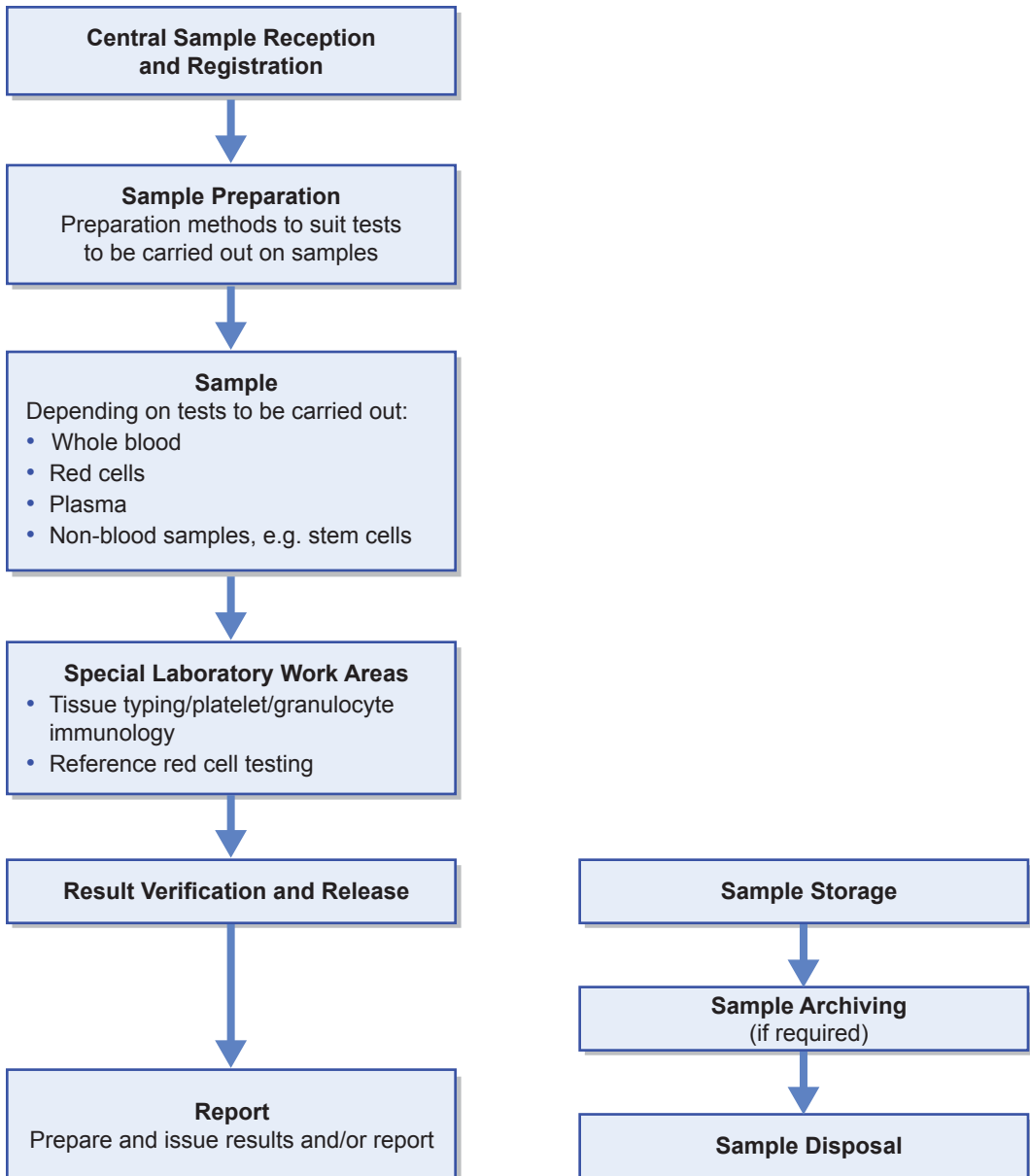


Figure 7. Laboratory process flow. Specialized testing

Schedule of spaces Laboratories – 100 units/day				
Space	Area	No.	Total	Comments
Blood Group Testing				
Office - serology manager	10	1	10	To local practice.
Office - scientists	13	1	13	To local practice.
Testing	24	1	24	May be all manual or a mixture of manual and automatic testing.
Infectious Disease Testing				
Office - virology manager	10	1	10	To local practice.
Office - scientists	9	1	9	To local practice.
Testing	30	1	30	May be all manual or a mixture of manual and automatic testing.
Quality Management				
While these spaces are located within the laboratory, they are part of Quality Management and are managed by the Quality Manager (QM).				
Office - QM supervisor	9	1	9	To local practice.
Quality Control laboratory	16	1	16	

Schedule of spaces
Laboratories – 100 units/day (continued)

Space	Area	No.	Total	Comments
Shared Facilities				
Specimen reception and preparation	10	1	10	
Clean room	12	1	12	For procedures requiring sterile conditions.
Gowning and preparation	6	1	6	Entry to clean room.
Clean up and glass washing	12	1	12	
Cool room (4°C)	8	1	8	Storage of post-testing donor samples.
Freezer (-20°C)	8	1	8	
Freezer cabinets	8	2	16	For refrigerator and freezer cabinets.
Sample archive cool room		1		Size will vary according to local retention period requirements.
Liquid nitrogen	8	1	8	Cryostatic specimen storage.
Reagent preparation/ Balance room	16	1	16	Includes balance.
Gowning	6	1	6	Air-lock to reagent preparation area.
Store	14	1	14	
Cleaner	5	1	5	
Hand washing	5	1	5	For hand washing and gowning at laboratory entry/exit.
Waste holding	6	1	6	
Meeting room - 10 seats	15	1	15	Allow 1.5 m ² per seat.
Laboratory Administration				
Office - laboratory manager	13	1	13	To local practice.
Office - central services	13	1	13	To local practice.
Office and/or workroom	14	1	14	Secretaries, faxing, photocopying, collating and binding.
Staff Amenities				
Beverage preparation	8	1	8	Refer to notes below.
Lunch room	12	1	12	
WC - female	4	1	4	
WC - male	4	1	4	
Circulation (30%)				

Schedule of spaces Laboratories – 100 units/day (continued)				
Space	Area	No.	Total	Comments
Tissue Typing				
Administration				
Documentation	9	1	9	Patient record storage.
Registration	9	1	9	Registration of samples in system.
Report	9	1	9	Results analysis and report preparation.
Sample				
Sample receipt	9	1	9	
Processing	9	1	9	
Serology			0	
Test Area	18	1	18	Preparation of tissue typing trays.
Tray Preparation	9	1	9	
Molecular				
Pre-amplification	12	1	12	PCR DNA extraction.
Post-amplification	16	1	16	PCR, gel electrophoresis.
Sequencing laboratory	12	1	12	Only required if DNA sequencing is carried out.
Dark room	9	1	9	
Solid Phase				
Flow cytometry area	12	1	12	Antibody screening.
Luminex area	12	1	12	Antibody identification.
Storage				
Freezer bay	10	1	10	Refrigerated and freezer cabinets for storage of patient samples, reagents, enzymes, reagent kits, buffers, etc.
Consumables	6	1	6	
Reagent store	6	1	6	
Circulation (30%)				

Schedule of Spaces

Laboratories – 100 units/day (continued)

Research and Development

The range and type of research that may be carried out in the blood centre laboratories is highly variable. It will be affected by the health status of the service population, the skills and interests of the staff and the level of available funding.

In a small laboratory, research and development are likely to be limited. Careful evaluation of the research and teaching program should be carried out prior to confirmation of space requirements

Additional Laboratory Services

A range of additional services and programmes may be carried out in the laboratory. They should reflect the health status of the service population, the skills and interests of the staff, and the level of available funding. Additional services may include:

- Red cell reference serology
- Platelet laboratory
- Cross match laboratory

Notes:

1: Hand washing and gowning: Depending on local policy, hand washing and gowning may be provided at a central entry/exit point to the entire laboratory unit or at the entry to each individual laboratory.

2: Staff amenities: Depending on local practice, staff amenities may be located at a central point for all blood centre staff or within each or selected departments. If staff amenities are centralized, it will be necessary to ensure that all laboratory staff carry out hand washing and gowning/ungowning whenever they leave the laboratories to use the amenities, or when they return.

3: Nucleic Acid Testing (NAT) is normally carried out at national or regional level. Fully automated NAT systems are now being introduced into some blood services. Where these are to be used, a dedicated room is required. The size of this room will be determined by the number and type of NAT systems unit being used.

Schedule of spaces Laboratories – 200 units/day (continued)				
Space	Area	No.	Total	Comments
Blood Group Testing				
Office - serology manager	10	1	10	To local practice.
Office - scientists	20	1	20	To local practice.
Testing	36	1	36	May be all manual or a mixture of manual and automatic testing.
Infectious Disease Testing				
Office - virology manager	10	1	10	To local practice.
Office - scientists	13	1	13	To local practice.
Testing	48	1	48	May be all manual or a mixture of manual and automatic testing.
Nucleic Acid Testing				
Laboratory	30	1	30	Space allows for 1 automated NAT system and support equipment.
Quality Management				
While these spaces are located within the laboratory, they are part of Quality Management and are managed by the Quality Manager (QM)				
Office - QM supervisor	9	1	9	To local practice.
Quality Control laboratory	24	1	24	

Schedule of spaces Laboratories – 200 units/day (continued)				
Space	Area	No.	Total	Comments
Shared Facilities				
Specimen reception and preparation	12	1	12	
Clean room	12	1	12	For procedures requiring sterile conditions.
Gowning and preparation	8	1	8	Entry to clean room.
Clean up and glass washing	18	1	18	
Cool room (4°C)	10	1	10	Storage of post-testing donor samples.
Freezer (-20°C)	12	1	12	
Freezer cabinets	10	2	20	For refrigerator and freezer cabinets.
Sample archive coolroom		1		Size will vary according to local retention period requirements.
Liquid nitrogen	8	1	8	Cryostatic specimen storage.
Reagent preparation/ Balance room	16	1	16	Includes balance.
Gowning	6	1	6	Air-lock to reagent preparation area.
Store	10	2	20	
Cleaner	5	1	5	
Hand washing	5	1	5	For hand washing and gowning at laboratory entry/exit.
Waste holding	6	1	6	
Meeting room - 12 seats	18	1	18	Allow 1.5 m ² per seat.
Laboratory Administration				
Office - laboratory manager	13	13	13	To local practice.
Office - central services	13	13	13	To local practice.
Office and/or workroom	18	18	18	Secretaries, faxing, photocopying, collating and binding.
Staff Amenities				
Beverage preparation	8	8	8	Refer notes below.
Lunch room	18	18	18	
WC - female	4	4	4	
WC - male	4	4	4	

Schedule of spaces
Laboratories – 200 units/day (continued)

Space	Area	No.	Total	Comments
Tissue Typing				
Administration				
Documentation	9	1	9	Patient record storage.
Registration	9	1	9	Registration of samples in system.
Report	9	1	9	Results analysis and report preparation.
Sample				
Sample receipt	9	1	9	
Processing	9	1	9	
Serology				
Test Area	38	1	38	
Tray Preparation	12	1	12	Preparation of tissue typing trays.
Molecular				
Pre-amplification	13	1	13	PCR DNA extraction.
Post-amplification	16	1	16	PCR, gel electrophoresis.
Sequencing laboratory	13	1	13	Only required if DNA sequencing is carried out.
Dark room	10	1	10	
Solid Phase				
Flow cytometry area	9	1	9	Antibody screening.
Luminex area	9	1	9	Antibody identification.
Storage				
Freezer bay	13	1	13	Refrigerated and freezer cabinets for storage of patient samples, reagents, enzymes, reagent kits, buffers, etc.
Consumables	6	1	6	
Reagent store	6	1	6	
Circulation (30%)				

Schedule of spaces

Laboratories – 200 units/day (continued)

Research and Development

The range and type of research that may be carried out in the BTS laboratories is highly variable. It will be effected by the health status of the service population, the skills and interests of the staff and the level of available funding.

A dedicated training laboratory may be provided in centres that have a significant teaching and training role.

Additional Laboratory Services

A range of additional services and programmes may be carried out in the laboratory. They should reflect the health status of the service population, the skills and interests of the staff, and the level of available funding. Additional services may include:

- Red cell reference serology
- Platelet laboratory
- Cross match laboratory

Notes:

1. Hand washing and gowning: Depending on local policy, hand washing and gowning may be provided at a central entry/exit point to the entire laboratory unit or at the entry to each individual laboratory.
2. Staff amenities: Depending on local practice, staff amenities may be located at a central point for all blood centre staff or within each or selected departments. If staff amenities are centralized, it will be necessary to ensure that all laboratory staff carry out hand washing and gowning/ungowning whenever they leave the laboratories to use the amenities, or, when they return.
3. Nucleic Acid Testing (NAT) is normally carried out at national or regional level. Fully automated NAT systems are now being introduced into some blood services. Where these are to be used, a dedicated room is required. The size of this room will be determined by the number and type of NAT systems unit being used.

Schedule of spaces Laboratories – 600 units/day				
Space	Area	No.	Total	Comments
Blood Group Testing				
Office - serology manager	10	1	10	To local practice.
Office - scientists	26	1	26	To local practice.
Testing	60	1	60	May be all manual or a mixture of manual and automatic testing.
Infectious Disease Testing				
Office - virology manager	10	1	10	To local practice.
Office - scientists	26	1	26	To local practice.
Testing	96	1	96	May be all manual or a mixture of manual and automatic testing.
Nucleic Acid Testing				
Laboratory	30	1	30	Space allows for 1 automated NAT system and support equipment.
Quality Management				
While these spaces are located within the laboratory, they are part of Quality Management and are managed by the QM manager.				
Office - two supervisors	13	1	13	To local practice
Quality Control Laboratory	52	1	52	

Schedule of spaces Laboratories – 600 units/day (continued)				
Space	Area	No.	Total	Comments
Shared Facilities				
Specimen reception and preparation	16	1	16	
Clean room	20	1	20	For procedures requiring sterile conditions.
Gowning and preparation	13	1	13	Entry to clean room.
Clean up and glass washing	18	1	18	
Cool room (4°C)	12	1	12	Storage of post-testing donor samples.
Freezer (-20°C)	18	1	18	
Freezer cabinets	13	2	26	For refrigerator and freezer cabinets.
Sample archive coolroom		1		Size will vary according to local retention period requirements.
Liquid nitrogen	13	1	13	Cryostatic specimen storage.
Reagent preparation/ Balance room	18	1	18	Includes balance.
Gowning	6	1	6	Air lock to reagent preparation area.
Store	13	2	26	
Cleaner	5	1	5	
Hand washing	5	1	5	For hand washing and gowning at laboratory entry/exit.
Waste holding	6	1	6	
Meeting room - 20 seats	35	1	35	Allow 1.5 m ² per seat.
Laboratory Administration				
Office - laboratory manager	13	1	13	To local practice.
Office - technical manager	13	1	13	To local practice.
Office - central services	26	1	26	To local practice.
Office - principal scientist	13	1	13	To local practice.
Office and/or workroom	36	1	36	Secretaries, faxing, photocopying, collating and binding.
Staff Amenities				
Beverage preparation	8	1	8	Refer notes below.
Lunch room	36	1	36	
WC - female	4	1	4	
WC - male	4	1	4	

Schedule of spaces Laboratories – 600 units/day (continued)				
Space	Area	No.	Total	Comments
Tissue Typing				
Administration				
Documentation	12	1	12	Patient record storage.
Registration	12	1	12	Registration of samples in system.
Report	12	1	12	Results analysis and report preparation.
Sample				
Sample receipt	12	1	12	
Processing	12	1	12	
Serology				
Test Area	64	1	64	
Tray Preparation	12	1	12	Preparation of tissue typing trays.
Molecular				
Pre-amplification	16	1	16	PCR DNA extraction.
Post-amplification	24	1	24	PCR, gel electrophoresis.
Sequencing laboratory	16	1	16	Only required if DNA sequencing is carried out.
Dark room	12	1	12	
Solid Phase				
Flow cytometry area	12	1	12	Antibody screening.
Luminex area	12	1	12	Antibody identification.
Storage				
Freezer bay	16	1	16	Refrigerated and freezer cabinets for storage of patient samples, reagents, enzymes, reagent kits, buffers, etc.
Consumables	8	1	8	
Reagent store	8	1	8	
Circulation (30%)				
<p>Note: Spaces required in Tissue typing will depend on the scope of services to be provided. As a guide, ASHI recommends that tissue typing laboratories should allow 3m² per task for each person working in these laboratories</p>				

Schedule of spaces

Laboratories – 600 units/day (continued)

Research and Development

The range and type of research that may be carried out in the BTS laboratories is highly variable. It will be effected by the health status of the service population, the skills and interests of the staff and the level of available funding.

A dedicated training laboratory may be provided in centres that have a significant teaching and training role.

Additional Laboratory Services

A range of additional services and programmes may be carried out in the laboratory. They should reflect the health status of the service population, the skills and interests of the staff, and the level of available funding. Additional services may include:

- Red cell reference serology
- Platelet laboratory
- Cross match laboratory

Notes:

1. Hand washing and gowning: Depending on local policy, hand washing and gowning may be provided at a central entry/exit point to the entire laboratory unit or at the entry to each individual laboratory.
2. Staff amenities: Depending on local practice, staff amenities may be located at a central point for all blood centre staff or within each or selected departments. If staff amenities are centralized, it will be necessary to ensure that all laboratory staff carry out hand washing and gowning/ungowning whenever they leave the laboratories to use the amenities, or, when they return.
3. Nucleic Acid Testing (NAT) is normally carried out at national or regional level. Fully automated NAT systems are now being introduced into some blood services. Where these are to be used a dedicated room is required. The size of this room will be determined by the number and type of NAT systems unit being used.

2.3.5 Quality Management

Concept

The Quality Management unit is responsible for all the co-coordinated activities that direct and control the BTS in regard to quality, including Quality Control (QC), Quality Assurance (QA), Planning, and Improvement. Some of the activities organized by the unit may include internal audit, document control, incident management (including adverse reaction reporting), biosafety and haemovigilance.

Quality assurance is the range of activities and systems that provide confidence within the organization and authorities that all quality requirements are met. Quality control involves the checks put in place to ensure that processes, procedures and products meet the quality requirements. There may be a Quality Control Laboratory which is specifically responsible for conducting testing of final products and other samples to meet quality specifications. This QC Laboratory is preferably located close to the other laboratories.

Scope of services

A Quality Management section provides a range of investigative and diagnostic services, which may include:

- Supervision of operations to ensure compliance with GMP, including audit requirements, internal quality control, external quality assurance programmes (EQAP), regulatory/licensure requirement and activities involved in accreditation of the centre. This should also include reporting and analysis of incidents and errors with effective corrective and preventive actions.
- Document management or document control ensures the important function of traceability. It manages preparation, issue and retrieval of documents which generates a significant amount of hard copy data and records for secure and long term storage which needs to be easily accessible.
- Evaluation and supervision of the products manufactured as well as the consumables, kits and reagents to ensure that specifications are met.
- Implementation and supervision of biosafety procedures.
- Establishment of a haemovigilance system for monitoring, reporting and investigating adverse incidents related to blood transfusion activities.

Workload

Quality Management workload will be determined by the operational requirements of the particular blood centre.

Hours of operation

The Unit will operate during normal office hours unless operational requirements demand otherwise.

Location and relationship

The QC laboratory can be located anywhere within the blood centre.

Functional content

Refer to 2.0 Schedules of Spaces. The Quality Management function will generate a significant amount of hard copy data and records that will require secure, long-term storage. These data and records must be readily accessible for internal and external audit.

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 selection 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

Mechanical ventilation system should be provided to toilets, tea rooms, and utility rooms as required by local regulations. In areas where air conditioning is not required, natural ventilation with ceiling fans can be considered.

Air conditioning

Where air conditioning (cooling and heating) is required, the condition of the rooms shall be maintained at:

- 240C ±20C DB/50% RH ± 10% in summer
- 210C ±20C DB/ 40% RH in winter

Lighting

The use of natural light should be maximized. Artificial electric lighting should be to the level and type appropriate for the work to be performed. Emergency lighting should be provided in the event of power failure and designed in accordance with current regulations.

Communication

Electronic communication should include telephone, facsimile and internet connections..

Schedule of spaces

Areas required for QC laboratories are included in the Testing Laboratories Schedule of Spaces and the areas required for Quality Management section are included in the Administration Schedule of Spaces.

2.3.6 Administration and management

Concept

The Administration and Management unit is responsible for the clerical, financial, information and administrative support services required to manage the blood transfusion service and its facilities.

Administrative and management organization varies greatly from country to country, but may include the following:

- (1) executive administration
- (2) administrative services (including facility management)
- (3) public affairs and marketing
- (4) human resources
- (5) finance
- (6) research and training
- (7) procurement and supply management
- (8) maintenance
- (9) biosafety and risk management
- (10) information and communication technology

Offices for other operations which may be co-located with Administration and Management are;

- donor recruitment and management
- clinical services

Scope of Services

Executive administration

This department manages and directs all activities within the BTS. It reports to and coordinates with the BTS and relevant national and/or provincial health authorities and regulatory bodies.

Administrative services

Administrative services provides administrative infrastructure to all units and departments within the blood transfusion facility, including personnel, administrative support, processes, procedures, procurement, security and the information required for data management.

Public affairs and marketing

This group maintains public education programmes, carries out media relations and promotes the image of the BTS. The sub-unit's efforts ensure on-going public support necessary to establish, expand and maintain an adequate pool of blood donors.

Donor recruitment and management

Donor recruitment manages the relationship between donors and BTS, including marketing, recruitment, donor files, demographic details and complaints. Donor recruitment and management may be a separate unit or a function of executive management. It is suggested to have this close to the donor collection areas.

Clinical (medical and nursing) services

Clinical services liaises with clinicians. Clinical services may be a separate unit or a function of executive management.

Quality management

This section manages the implementation of organizational quality management policies and regulatory requirements. (Refer to section 2.3.5)

Human resources

Human resources is responsible for recruiting and maintaining the skilled workforce required by the BTS.

Finance

Finance provides the financial management required to establish the BTS budget and works with the administrative services subunit to ensure that it operates within this budget. Its other responsibilities include cash flow control, forward planning and the consideration of capital in operational considerations.

Research and training

This section provides initial and on-going training and learning opportunities for BTS staff. The team may also be engaged with other health service delivery staff who is

involved in transfusion services or the collection and use of blood and blood products. Adequate provisions for training facilities include training laboratories and rooms and a library should be included.

Biosafety and risk management

This group establishes biosafety and risk management policies and oversees the ongoing application of these policies at the blood centre and across the BTS.

Information and communication technology (ICT)

ICT manages the information and communication technology used at the blood centre including hardware and software procurement, integration and application and hardware maintenance.

Hours of operation

The administration unit generally operates during normal office hours, but units responsible for public or donor education may be required to run evening or weekend programmes. After-hours services are essential for some services, e.g. medical support and liaison for donors and hospitals.

Location and relationship

While it is recommended that the Administration unit should be co-located with Processing and the Testing Laboratories, it has little need for day-to-day direct contact with either of these units. However a close relationship with the collection area should be considered.

Functional content

Offices and the required filing and technical support areas should be provided to each unit. Lecture theatres, tutorial rooms, flexible training spaces and a library will be required by the research and training unit.

Meeting rooms and toilets should be shared by the entire unit. Meeting rooms have been identified by units to assist in determining the number required, but they are a shared facility.

Engineering Services

Mechanical ventilation

Mechanical ventilation systems should be provided to toilets, tea rooms and utility rooms as required by local regulations. In areas where air conditioning is not required, natural ventilation with ceiling fans can be considered.

Air conditioning

The provision of air-conditioning to offices should follow national standards. Where air conditioning (cooling and heating) is required, the condition of the rooms should be maintained at:

- 24°C ±2°C DB/50%RH in summer
- 20°C ±2°C DB/40% RH minimum in winter

Lighting

Use of natural light should be maximized. Artificial electric lighting should be to the level and type appropriate for the work to be performed. Emergency lighting should be provided in the event of power failure and designed in accordance with current regulations.

Communication

Electronic communication should include telephones and facsimiles. A PABX system with adequate incoming line and outgoing extension for the office administration, as well as the laboratories and blood processing facilities should be provided.

Schedule of spaces Administration – 100 units/day				
Space	Area	No.	Total	Comments
Executive				
Office - Director BTS	12	1	12	To local practice
Office - Deputy Director	12	1	12	To local practice
Executive secretary	8	1	8	To local practice
General secretaries	13	1	13	To local practice
Administration filing	9	1	9	
Waiting room	9	1	9	
Pantry	4	1	4	Beverage preparation
Administration Services				
Office - BTS manager	9	1	9	To local practice.
Office - procurement manager	9	1	9	To local practice.
General office	13	1	13	To local practice.
IT/server room	12	1	12	
Secretary	7	1	7	To local practice.
Conference room	16	1	16	Shared by all sections of administration.
Meeting room	12	1	12	Shared by all sections of administration.
Mail room	9	1	9	
PABX	6	1	6	
Security centre	9	1	9	
Public reception and switchboard	8	1	8	Serves entire facility. Main entrance to Blood Centre
Waiting	12	1	12	Serves entire facility
Public Affairs and Marketing				
Office - Manager	9	1	9	To local practice.
Office - General	9	2	18	To local practice.
Resource centre	12	1	12	
Human Resource				
Office - personnel and payroll manager	9	1	9	To local practice.
General office	9	1	9	To local practice.
Filing	7	1	7	

Schedule of spaces Administration – 100 units/day (continued)				
Space	Area	No.	Total	Comments
Finance				
Office - finance manager	9	1	9	To local practice.
Secretary	7	1	7	To local practice.
General office	13	1	13	Book-keeper, accounts payable, costing & printer.
Filing	9	1	9	
Education and Training				
Office - manager	9	1	9	To local practice.
Conference/meeting room (12 seats)	18	2	36	Allow 1.5 m ² per seat. Distribute other meeting rooms and tutorial rooms throughout the blood centre.
Stacks	18	1	18	
Journal Storage	8	1	8	
Reading Area	9	1	9	
Donor Recruitment				
General office	9	1	9	To local practice.
Store	9	1	9	Stationery and recruitment materials.
Clinical Services				
Office - medical director	9	1	9	To local practice.
General office	13	1	13	To local practice.
Quality Management				
Office - Quality manager	9	1	9	To local practice
Document control	9	1	9	
Document store	9	1	9	
Staff Amenities				
Toilet - female	3	1	3	1 WC pan, 1 washbasin
Toilet - male	3	1	3	1 WC pan, 1 washbasin
Pantry	6	1	6	
Circulation (30%)				

Schedule of spaces**Administration – 200 units/day**

Provision of administrative positions and staff levels will vary depending on the blood centre organization, service role and local practice. Spaces below are indicative only

Space	Area	No.	Total	Comments
Executive				
Office - Director BTS	15	1	15	To local practice.
Office - Deputy Director	15	1	15	To local practice.
Executive secretary	8	1	8	To local practice.
General secretaries	13	1	13	To local practice.
Administration filing	12	1	12	
Waiting room	12	1	12	
Pantry	4	1	4	Beverage preparation.
Administration Services				
Office - BTS manager	9	1	9	To local practice.
Office - records manager	9	1	9	To local practice.
Office - IT manager	9	1	9	To local practice.
Office - procurement manager	9	1	9	To local practice.
General office	13	1	13	To local practice.
IT/server room	12	1	12	
Secretary	7	1	7	To local practice.
Conference room	18	1	18	Shared by all sections of administration.
Meeting room	12	2	24	Shared by all sections of administration.
Mail room	9	1	9	
PABX	6	1	6	
Security centre	9	1	9	
Public reception and switchboard	8	1	8	Serves entire facility. Main entrance to blood centre.
Waiting	16	1	16	Service entire facility.
Public Affairs and Marketing				
Office - Manager	9	1	9	To local practice.
Office - General	9	3	27	To local practice.
Resource centre	16	1	16	

Schedule of spaces Administration – 200 units/day (continued)				
Space	Area	No.	Total	Comments
Human Resource				
Office - personnel manager	9	1	9	To local practice
Office - pay-roll manager	9	1	9	To local practice
General office	13	1	13	To local practice
Filing	9	1	9	
Finance				
Office - finance manager	9	1	9	To local practice
Secretary	7	1	7	To local practice
General office	13	1	13	Book-keeper, accounts payable, costing & printer
Filing	9	1	9	
Education and Training				
Office - manager	9	1	9	To local practice
General office	13	1	13	To local practice
Conference room (20 seats)	30	2	60	Allow 1.5 m ² per seat. Distribute other meeting rooms and tutorial rooms throughout the blood centre.
Stacks				
Journal Storage	28	1	28	
Reading Area	8	1	8	
Filing	9	1	9	
	6	1	6	
Donor Recruitment				
General office	12	1	12	To local practice
Store	12	1	12	Stationery and recruitment materials
Clinical Services				
Staff sick bay	7	1	7	To local practice
Office - medical director	9	1	9	To local practice
Office - nurse manager	9	1	9	To local practice
General office	9	1	9	To local practice

Schedule of spaces
Administration – 200 units/day (continued)

Space	Area	No.	Total	Comments
Quality Management				
Office - Quality manager	9	1	9	To local practice
General office	9	1	9	To local practice
Document control	9	1	9	
Document store	9	1	9	
Subtotal			36	
Staff Amenities				
Toilet - female	3	1	3	1 WC pan, 1 wahbasin
Toilet - male	3	1	3	1 WC pan, 1 wahbasin
Pantry	6	1	6	
Subtotal			12	
Circulation (30%)				

Schedule of spaces**Administration – 600 units/day**

Provision of administrative positions and staff levels will vary depending on the blood centre organization, service role and local practice. Spaces below are indicative only

Space	Area	No.	Total	Comments
Executive				
Office - Director BTS	15	1	15	To local practice.
Office - Deputy Director	15	1	15	To local practice.
Executive secretary	8	1	8	To local practice.
General secretaries	26	1	26	To local practice.
Administration filing	16	1	16	
Waiting room	15	1	15	
Pantry	4	1	4	Beverage preparation.
Administration Services				
Office - BTS manager	9	1	9	To local practice.
Office - records manager	9	1	9	To local practice.
Office - IT manager	9	1	9	To local practice.
Office - procurement manager	9	1	9	To local practice.
General office	26	1	26	To local practice.
IT/server room	16	1	16	
Secretary	7	1	7	To local practice.
Conference room	28	1	28	Shared by all sections of administration.
Meeting room	12	4	48	Shared by all sections of administration.
Procurement and supply room				
Mail room	10	1	10	
PABX	6	1	6	
Security centre	12	1	12	
Public reception and switchboard	8	1	8	Serves entire facility. Main entrance to blood centre.
Security centre				
Waiting	24	1	24	Service entire facility.
Public Affairs and Marketing				
Office - Manager	9	1	9	To local practice.
Office - General	9	3	27	To local practice.
Resource centre	28	1	28	

Schedule of spaces
Administration – 600 units/day (continued)

Space	Area	No.	Total	Comments
Quality Management				
Office - Quality manager	9	1	9	To local practice
General office	13	1	13	To local practice
Document control	13	1	13	
Document store	12	1	12	
Subtotal			47	
Staff Amenities				
Toilet - female	6	1	6	2 WC pans, 2 wahbasins
Toilet - male	6	1	6	1 WC pan, 2 wahbasins, 1 urinal
Pantry	6	1	6	
Subtotal			18	
Total net area			777	
Circulation (30%)			233	

2.3.7 Engineering Department

Concept

The Engineering Department has three roles:

- (1) management and maintenance of engineering services
- (2) management and maintenance of the central plant.
- (3) biomedical equipment maintenance

The department may also maintain and service BTS vehicles or be responsible for outsourcing this function. The central plant, which includes the engineering equipment and the building in which it is housed, serves the entire blood centre.

While the Engineering Department will be responsible for the repair of any malfunctioning or broken equipment, its aim is to prevent equipment breakdown by effective preventive and routine maintenance. (Refer Appendix C: Facility Manager Role Statement)

Scope of services

Engineering services is responsible for

- (1) preventive and routine maintenance of the building, engineering services and major engineering equipment, including boilers, steam, chillers, air handling units, and cool rooms
- (2) the repair of any of these engineering services or pieces of equipment in the event of breakdown or malfunction
- (3) biomedical equipment maintenance
- (4) ground maintenance
- (5) routine housekeeping
- (6) management of bulk stores
- (7) waste management
- (8) vehicle servicing and maintenance

These services may be provided in-house or provided by external contractors. If these services are provided by external contractors the centre must have adequate engineering expertise of its own to manage and evaluate the services being provided by these contractors.

The Engineering Department will manage minor building works projects where appropriate.

Workload

The Engineering Department is responsible for the continuous, safe and optimal operation of engineering systems within the premises so that operating conditions for different units are maintained. Staff should be available to attend to engineering issues at all times.

Hours of operation

Engineering services operates during normal office hours, but on-call staff must be available 24 hours a day, seven days a week in case of emergencies. The unit will also arrange for trades persons to be available seven days a week.

Location and relationship

The engineering plant rooms shall be centralized in the facility to minimize the length of recirculation of services. The substation will need to be on the ground floor level and the air conditioning plant will be probably on the roof. The engineering office and workshop shall be close to the central part. The Engineering Department should be located in a service zone away from any areas of public access. It should have good road access for service and delivery.

Building fabric

Office accommodation should be to a standard similar to that throughout the facility.

The bulk store, engineering workshop, waste holding areas and central plant should have robust, impact-resistant finishes. Materials should also be chosen for ease of cleaning.

Functional content	
Workshop	To accommodate a range of trade persons including painters, carpenters, mechanics, electricians and general handymen. Tools such as drills and mills will be provided in the workshop.
Office	Facility engineer, close to workshop.
Bulk store	For blood transfusion facility requirements.
Engineering store	For Engineering Department.
Central plant	
Waste holding	
Contaminated waste holding	
Staff toilet	
Garage	For parking and maintenance of blood transport vehicles and mobile collection units if used.
Equipment washing	Cleaning of refrigerated blood transportation and storage containers.

Engineering services

Mechanical ventilation. Mechanical ventilation system should be provided to all plant rooms and the mechanical workshop as required by the local regulations. Where carpentry work is carried out in workshop, a special dust collection system should be used.

Air conditioning Air conditioning is only required in the engineering office. This should be provided in accordance with local practice.

Lighting

Use of natural light should be maximized. Artificial lighting should be to the level and type appropriate for the work to be performed. Emergency lighting should be provided in the event of power failure and designed in accordance with current regulations.

Communication

Telephone, facsimile and data services should be provided in the engineering office and workshop. BAS, FIP and EWIS terminals (may be mimic panels only) should be located in the engineering office so that the facility engineer is aware of the conditions of the engineering services in the premises at all time.

Schedule of spaces Engineering				
Space	Area	No.	Total	Comments
Engineering Services				
Office - engineer	14	1	14	Office, plan filing and layout space
Office - biomedical engineer	9	1	9	
Workshop - engineering maintenance	36	1	36	
Workshop - biomedical equipment maintenance	25	1	25	
Engineering store	16	1	16	
Bulk store	52	1	52	
Housekeeping				
Laundry	7	1	7	Cleaning materials
Store	7	1	7	
Waste Management				
Waste holding - general	24	1	24	
Waste holding - contaminated	9	1	9	

Central Plant

Indicative areas are given for the engineering central plant as variations due to locally available fuel, climatic conditions, dependability of mains power supply, regulatory requirements and other variable inputs affect plant requirements and area.

Mechanical Services

Chiller Plant Room (water-cooled chillers)

1000 kwr	78	6 m x 13 m	Allowance included for chillers, pumps and mechanical switchboard.
2000 kwr	98	7 m x 14 m	
3000 kwr	255	15 m x 17 m	

Heat Rejection Equipment (water-cooled, roof-mounted cooling towers)"

1000 kwr	90	9 m x 10 m	Cooling towers are normally located on the roof in fully louvred enclosures to permit maximum air flow.
2000 kwr	108	9 m x 12 m	
3000 kwr	150	10 m x 15 m	

Chilled Water Plant (air cooled)

1000 kwr	104	8 m x 13 m	Air-cooled chillers are normally located on the roof in fully louvred enclosures to permit maximum air flow
2000 kwr	139	13 m x 13 m	
3000 kwr	234	13 m x 18 m	

Mechanical Service risers (multistorey facility)

Air duct riser	10	2 m x 5 m	Depending on building configuration Allowance should be made for separate exhaust flues to each fume cupboard and safety hood.
Exhaust air duct riser	10	2 m x 5 m	
Pipe and flue riser	10	2 m x 5 m	Depending on building configuration

Air Handling Plant

Supply air handling	88	8 m x 11 m	Depending on floor size, allow one plant room of this size on each floor
Exhaust fans and fume cupboard exhausts	48	6 m x 8 m	Fans installed on rooftop plant platform. Fume cupboard flues to discharge at least 3 m above adjacent roof.

Electrical Services Substation

500–2000 kVA	24	4 m x 6 m	If possible, locate on ground level. If located in the basement, additional space should be provided for a transformer access hatch. If located on a floor other than the ground floor, dry type or totally enclosed type transformer(s) should be used.
2 x 2000 kVA	60	6 m x 10 m	
3 x 2000 kVA	90	6 m x 15 m	

Main Switch Room

500–2000 kVA	18	3 m x 6 m
2 x 2000 kVA	30	5 m x 6 m
3 x 2000 kVA	40	5 m x 8 m

Main switch room should be located adjacent to the substation. If this is not possible, locate it above or below the substation.

Electrical Riser Room (for multilevel facilities)	12 m per floor minimum
---	------------------------

Should be located in line vertically to permit straight cable riser routing.

Standby Generator

Up to 1000 kVA	40	5 m x 8 m
Up to 2000 kVA	60	6 m x 10 m

Generator room should be located close to building perimeter to permit air intake and exhaust with necessary sound silencers and attenuators. Make allowance for in-ground fuel. Ensure truck access to fuel filling.

2 x 2000 kVA	100	10 m x 10 m
3 x 2000 kVA	140	10 m x 14 m

Communication Services

Main Distribution Frame

Single carrier	20	4 m x 5 m
Multiple carrier	30	5 m x 6 m

Locate close to site boundary on ground or in basement to permit simple cable entry routes

Communication rooms	12 per floor minimum	3 m x 4 m
---------------------	----------------------	-----------

Should be located in line vertically to permit straight cable riser routing.”

LAN/server room	40	5 m x 8 m
-----------------	----	-----------

Will vary depending on system requirements and network capacity. Room to be air conditioned 24 hours a day. Environmental conditions should be monitored at all times. Sometimes, a raised flooring system may be required.

PABX room	30	5 m x 6 m
-----------	----	-----------

May need to be larger depending on capacity of PABX system. Room to be air conditioned 24 hours a day. Environmental conditions monitored at all times. service.

General Spaces

Flammable liquid store	10	1
Water treatment plant	10	1
Liquid nitrogen store	8	1
Gas bottle store	8	1

For central reagent storage and decanting.

Fire control room/fire pump room	12	1	If mains water pressure is inadequate a tank and pump will be required.
Container cleaning	7	1	Cleaning of refrigerated blood transport containers.
Container store	11	1	Refrigerated blood transport containers awaiting cleaning.
Mobile collection store	16	1	Storage of mobile collection centre equipment and furniture.
Staff toilet	3	1	
Staff lounge	8	1	
Water resevoir			Only required if local water supply is inadequate to meet operational demands
Liquid waste treatment			Separate tanks for the containment and treatment of chemical and biohazardous liquid waste.

3 Design Brief

3.1 Facility Planning and Design – General Considerations

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

- (1) attractive to donors and the public, and
- (2) safe and efficient for staff.

The planning of the facility should reflect the requirements described in the functional brief, providing appropriate areas and relationships between spaces and departments and clearly defined open and secure areas. Circulation routes should be clear and direct while providing appropriate traffic separation.

The building design should respond to local climatic conditions and embody environmentally sustainable design (ESD) in its orientation, sun control and material selection.

Landscaping and planting should be used to enhance the building and provide a pleasant view from inside.

Modular planning should be utilized to simplify documentation, construction and to maximize flexibility for future change.

Disabled access should be provided in accordance with local regulations.

3.2 Site Selection

When selecting the site for a blood centre, the following requirements should be considered:

If the blood centre includes a collection centre, it is important that the site is easily accessible to the public by public transport.

The site should be readily accessible to transport vehicles to and from collection centres and hospitals.

The site should be flat for the ease and economy of development.

Adequate services including water and power should be available to the site.

The foundations/geological conditions should be suitable for the height of the proposed building. This may require geological investigation prior to site purchase.

The site must be above the local flood plain if flooding is a possibility in the area.

The site should be large enough to accommodate the proposed blood centre building, internal roads and parking for centre, staff and donor vehicles. To determine if the site is large enough it may be necessary to carry out “proof planning” prior to site purchase.

3.3 Good Manufacturing Practices (GMP)

The implementation and enforcement of Good Manufacturing Practices (GMP) in blood centres 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 centre facilities is essential to ensure that the collection and manufacturing environment will allow the production of blood and blood products of consistent quality.

3.4 Building Elements Substructure (Foundations)

Geotechnical conditions should be determined to establish allowable bearing pressure, stability, water-table level and likelihood of long-term settlement. The building substructure should be designed to suit these conditions.

Superstructure

The building superstructure should be designed to carry all dead and imposed loading.

Reference should be made to the Schedule of Equipment to determine the weight and location of all pieces of heavy equipment and to ensure that the structure is adequate for these loads.

In some locations, the superstructure may have to be designed to resist earthquake and cyclonic wind loads.

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.

Floors

Both on-ground and suspended (upper) floors should be designed to carry all dead and imposed loading. Structural systems should permit the level of floor penetrations required in the building. Consideration should be given to acoustic performance and fire resistance where appropriate.

Doors

External doors should be weatherproof. Internal doors 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

Door widths should be selected to suit door usage. Generally door sizes should be:

- 950 mm wide in all donor areas
- 1200 mm wide to all assisted toilets
- 1200 mm wide in all locations where donors may be transported by trolley
- to a 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:

- automatic closers for all fire and smoke doors
- escape hardware for all fire doors and doors on fire exit paths including fire escape stairs
- security access control for selected doors. Preference should be given to proximity card readers, but when this system is not available, keypad locks or key-operated locks may be used

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 paint or specialist 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.

Walls exposed to heavy traffic or impact may use an impact protection dado to a minimum height of 900 mm.

Floor Finishes

Generally, floor finishes should be low maintenance and easy to clean.

In laboratories, processing areas, donation and checking areas and all areas where blood is handled, 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, donation and checking 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 fibre 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 fibre 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	2700 mm
Corridors	2700 mm generally 2400 mm locally
Cool rooms	2400 mm
Freezers	2400 mm
Toilets, shower	2400 mm
Stores	2400 mm

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	1700 mm
Offices	1400 mm

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 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.

3.5 Engineering Services

Building Automation Systems (BAS)

Where technology and adequate staff are available, a 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 reliable engineering services and efficient use of energy.

Heating, Ventilation and Air Conditioning

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

The proposed conditions are:

- $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$ DB
- $50\% \pm 20\%$ RH in summer
- $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$ DB
- $50\% \pm 20\%$ RH 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:

- $24^{\circ}\text{C} \pm 2^{\circ}\text{C}$ DB in summer
- $21^{\circ}\text{C} \pm 2^{\circ}\text{C}$ DB in winter

A separate air conditioning plant should be provided for the processing and testing facilities and the office and donor 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

In areas where *Legionella pneumophila* (causative agent of Legionnaires' disease) is a potential problem, an air-cooled instead of water-cooled air conditioning system should be considered.

Ventilation

For BSL2 and BSL3 laboratories, a specific pressure control scheme has to be put in place for virus and bacteria control purposes. In BSL3 laboratories, HEPA filters and self-contained air conditioning system should be provided.

The exhaust system for toilets, car park and tea rooms and should comply with local legislation.

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 where 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.

Fume Cupboards and Safety Hoods

Fume cupboards and safety hoods should be operational at all time to maintain a negative pressure regime in the laboratory. Fume exhaust should be ejected and dispersed from stacks on the roof into the atmosphere (not deposited on adjacent

properties, buildings or tenants). Stacks should extend 6 m above the roofline and the tallest nearby building. Because stack supports are expensive and multiple stacks are unsightly, it is common for exhaust pipes to be clustered together (a maximum of six exhaust pipes per stack). It is natural to locate the fume cupboards and laboratories on the top floor, close to the roof.

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:

- Refrigeration equipment to all cool rooms and freezer rooms
- All refrigerator and freezer cabinets
- 50% of general lighting
- Emergency lighting system
- Central alarm system
- Collection, 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 neighbours. Consult with the local environmental protection agency for the required noise control for the system.

Power Quality Protection

The incoming power supply to a blood centre may be contaminated or unreliable to the extent that it can compromise the operation of the centre by affecting critical pieces of equipment. Precautions should be taken to protect the centre 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 neighbourhood 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. *Lightning surges*. A lightning strike to an overhead line providing power to the blood centre can cause a power surge.
3. *Harmonic distortions*. These are distortions in power due to other loads within the blood centre that generate harmonics. In this case, both voltage and current harmonics can be transmitted to the critical mission loads.
4. 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, similar to Form 3 configuration of AS 3439 (or equivalent standard), 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.

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 colour-coded to indicate the source of power supply (e.g. white for normal power supply, red for essential and blue for UPS) 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 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 upto 700 lux may be used. In donor areas, colour-corrected lamps should be used to observe the true colour of the donor's skin.

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 lighting system should be provided throughout 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 fibre 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 temperature 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 and local building regulations, 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.

The waste disposal method in the premises should comply with the local regulations. For Greenfield sites, consider collecting and re-using rain water for irrigation or flushing purposes.

If an anaerobic sewage system (such as a bio-drum system) is used, the effluent should be considered for irrigation water purposes.

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 multi-storeyed, 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 centre. 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. An electrical traction lift (elevator) should be considered for buildings higher than three levels.

Annex A. Reference Documents

The following documents are a useful source of information to the design team and Blood Centre managers. Reference should be made to these documents to provide additional detailed information not contained in the Guidelines, or where there are no local standards or regulations covering specific requirements.

Aide Memoire for National Blood Programmes. Quality Systems for Blood Safety. World Health Organization

Laboratory Biosafety Manual – Third Edition. World Health Organization. 1983

Safe Management of Waste from Healthcare Activities. World Health Organization, 2000

The Blood Cold Chain. Guide to selection and procurement of equipment and accessories. World Health Organization, 2002.

PIC/S GMP Guide for Blood Establishments

Australian Code of Good Manufacturing Practice – Human Blood and Tissues; Therapeutic Goods Administration, Canberra, Australia, 2000. Available at: <http://www.tga.health.gov.au/docs/pdf/gmpbltic.pdf>.

Guidelines for Certification of Facilities/Physical Containment Requirements. Office of the Gene Technology Regulator, ACT, Australia, July 2002. .

Laboratory Design and Construction – General Requirements. Australian Standard AS 2982,1997.

Safety in Laboratories. Australian Standard AS 2243

Part 1v- 1997 General

Part 2 - 1997 Chemical Aspects

Part 3 - 2002 Microbiology

Part 4 - 1998 Ionizing Radiation

Part 6 - 1990 Mechanical Aspects

Part 7 - 1991 Electrical Aspects

Part 8 - 2001 Fume Cupboards

Part 9 – 1991 Recirculating Fume Cabinets

Part 10 - 1991 Storage of Chemicals

Biological Safety Cabinets- Installation and Use. Australian Standard AS/NZS 3666-2006, parts1-3. Air Handling and Water Systems in Buildings – Microbiological Control.

Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components. 9th edition. Australian Standard AS 3666. Strasbourg, Council of Europe Publishing, 2003.

AABB Technical Manual. 14th edition. American Association of Blood Banks. Bethesda, Maryland, 2002.

Annex B. Useful Websites

www.who.int Home page of the World Health Organization.

www.who.int/bct Website of the World Health Organization, Department of Blood Safety and Clinical Technology.

www.picscheme.org/publications Website of Pharmaceutical Inspection Co – Operation Scheme. Copies of GMP Guide for Blood Establishments can be downloaded from this site.

www.health.gov.au/tga Website of the Australian Therapeutic Goods Administration.

www.ogtr.gov.au Website of the Office of the Gene Technology Regulator. Copies of Guidelines for Certification of Facilities/Physical containment Requirements can be downloaded from this site.

www.official-document.co.uk Copies of Guidelines for Blood Transfusion in the United Kingdom can be downloaded from this site.

www.standards.com.au Website of the Australian Standards Association.

www.iso.ch Website of the International Organization for Standardization.

www.aabb.org Website of the American Association of Blood Banks.

<http://www.isbt-web.org/> Website of the International Society of Blood Transfusion.

<http://www.ashi-hla.org> Website of the American Society of Histocompatibility and Immunogenetics

<http://www.aseatta.org.au> Website of the Australasian and South East Asian Tissue Typing Association

Annex C. Role of Facility Manager

The role of the facility manager is to ensure that conditions appropriate for blood transfusion facilities are maintained at all times, and that the most optimal operation cost is attained. The facility manager may be a member of the blood centre staff or may be a staff member of an external service provider contracted to manage the blood centre building and engineering services.

The facility manager should:

- be involved in the design of the building in order to ensure redundancy of necessary systems, e.g. power backup systems, and to review cost-effectiveness of the design from an operational perspective;
- be involved with the commissioning and checking of the operation and maintenance manuals at the practical completion of the project;
- be properly trained by each of the trade subcontractors on all the systems installed in the premises;
- ensure compliance with all relevant legislation, e.g. Essential Services and Occupation Health and Safety and disabled access standards;
- be familiar with the equipment and plants installed in the building;
- be responsible for the continuing storage and maintenance of all manuals, drawings and specifications required for the operation of the building and major equipment;
- maintain a full set of tools required for the maintenance of the buildings and equipment;
- schedule preventive maintenance and record results (utilize computerized maintenance management system software packages such as PCMAINT, PEMAC, PSDI MAXIMO);
- develop procedures for operation of major plant;
- develop procedures for operations staff to handle emergencies including fire, bomb threat, power failure, communication failure;
- monitor energy costs and develop trends of operation costs by category, such as electrical costs, chiller running costs, and gas costs;
- provide continuous training of trade and other support staff in operating the system effectively;
- utilize communication devices such as mobile phones, pagers and two-way radios to facilitate a quick response in normal and emergency conditions;
- if technology permits, remotely monitor and diagnose the building engineering system via modem or dial-in facilities when off-site;
- be aware of up-to-date techniques in effective management of the building systems, and maintain currency with all relevant codes and legislation; and
- prepare budgets for annual maintenance and recurrent costs, and for periodic upgrades of major plants requiring either major refurbishment or replacement.

Maintenance

The facility manager shall be responsible for routine maintenance of the blood transfusion facility's engineering services and equipment.

Essential Services

The facility manager shall carry out maintenance of essential services as per manufacturers' and local regulatory requirements.

- Emergency Lighting System – Level 1 discharge test every 6 months.
Level 2 discharge test, cleaning and re-lamping, as required, every 12 months.

- Automatic Sprinkler System – Level 1 weekly.
Level 2 monthly.
Level 3 every 6 months.
Level 4 annually.
Level 5 every 3 years.
Level 6 every 6 years.

- Fire Hydrant System – Level 1 weekly.
Level 2 monthly.
Level 3 every 6 months.
Level 4 annually.
Level 5 every 3 years.
Level 6 every 6 years.

- Hose Reel System – Level 1 every 6 months.
Level 2 annually.

- EWIS System – Level 1 weekly.
Level 2 monthly.
Level 3 annually.

- Fire Detection and Alarm – Level 1 weekly.
Level 2 monthly.
Level 3 annually.

- Mechanical Services related to Smoke Management Level 1 weekly .
Level 2 monthly.
Level 3 quarterly.
Level 4 annually.

- Fire Extinguisher Level 1 half yearly.
Level 2 annually.
Level 3 every 3 years.
Level 4 every 6 years.

Electrical Services

The facility manager shall carry out maintenance of electrical services according to the manufacturer's recommendations. He or she shall also:

- service the main switchboard annually;
- undertake a thermal scan of the main switchboard biannually;
- check distribution boards annually;
- clean and check light fittings annually;
- re-lamp according to manufacturer's recommendation;
- review energy consumption annually and compare with energy target;
- test diesel generator monthly on a minimum 50% load, either on the building load or on a dummy load;
- check fuel storage capacity regularly;
- check fuel sample test annually;
- check fuel tank integrity biannually;
- check UPS annually; and,
- check individual battery output annually.

Mechanical Services

The facility manager shall carry out maintenance of mechanical services according to the manufacturer's recommendations.

- Chiller maintenance – Level 1 every 6 months.
Level 2 annually.
Level 3 every 2 years.
- Cooling tower water treatment – Level 1 monthly.
Level 2 every 6 months.
Level 3 annually.
- Boiler maintenance – Level 1 monthly.
Level 2 every 6 months.
- Air handling units – Level 1 monthly.
Level 2 every 6 months.
Level 3 annually.
- Filters – Check pressure drop and clean or replace according to manufacturer's recommendations.
- Cooling/heating coils – Clean annually.
- BAS – Check control strategy regularly.
- Mechanical services switchboard – same as main switchboard .
- Pump maintenance – Level 1 monthly .
Level 2 every 6 months.
Level 3 annually.

Hydraulic Services

- Check all drainage and tundishes for blockage regularly.
- Check storage tank and organize waste removal regularly.
- Back-wash reverse-osmosis filtration plant as per manufacturer's recommendation.
- Service reverse-osmosis filtration plant annually.
- Regularly service all water pumps.
- Regularly clean water tanks.
- Ensure all water seal traps are functional.
- Check and maintain water filtration system to manufacturer's recommendation where applicable.
- Regularly clean strainers and waste traps.

Lift Services

- Regular lift maintenance – Level 1 monthly.
Level 2 annually.
Level 3 every 3 years.

Annex D. Glossary

Blood Transfusion Services(s)

Throughout these design guidelines, the term blood transfusion services (BTS) is used. This term refers to the organization that collects, processes, stores, transports, and distributes human blood and blood components intended for transfusion. Some services may, in addition, provide diagnostic services in immunohaematology or tissue typing, maintain and dispense plasma derivatives, and store and provide tissue. Within countries, there may be one centralized national BTS (BTS) serving the entire country, or there may be several regional BTS with central management oversight and coordination.

Blood Centre

The term “blood centre” used in the guidelines refers to the building that houses the BTS administration, blood processing, testing laboratories, inventory storage and distribution and associate support services. It may also house a blood collection facility.

Mobile Collections

A collection facility, including all required furniture and equipment, that is set up in a specially designed vehicle or bus and driven to a collection location.

Demountable Collection Centres

Demountable collection centres are set up in existing buildings for short periods, usually less than five days, for blood collection purposes and demounted at the end of this period. All furniture and equipment required for the centre is carried in a vehicle, usually based at the blood centre, to and from the collection location.

Annex E. Abbreviations

ASHI	American Society of Histocompatibility and Immunogenetics
ASEATTA	Australasian and South East Asian Tissue Typing Association
BAS	building automation system
BSL2	biosafety level 2
BSL3	biosafety level 3
BTS	blood transfusion service
CPU	Central processing unit
DB	Dry bulb temperature
ESD	environmentally sustainable design
EWIS	early warning intercommunications system
FIP	fire indicator panel
ICT	Information and Communication Technology
GMP	good manufacturing practices
HEPA	high-efficiency particulate air (filter)
LAN	local area network
NAT	nucleic acid amplification testing
PABX	Private automatic branch exchange
QC	quality control
QM	quality manager
RCD	residual current device
RH	relative humidity
UPS	uninterrupted power supply
UTP	Unshielded twisted pair (data cable)

Annex F. Acknowledgements

The WHO Regional Office for the Western Pacific acknowledges the contribution of the following individuals and organizations in the preparation of these guidelines:

Dennis Martin

Dennis Martin and Associates
Health and Science Facility Planners
Melbourne, Australia

Dr Erica Wood

Australian Red Cross Blood Services
Melbourne, Australia

Associate Professor Elizabeth M. Dax

National Serology Reference Laboratory,
Melbourne, Australia

Allan Cheng

Umwol Lai and Associates
Building Services Engineers
Melbourne, Australia

Dr Diana Teo,

Blood Services Group
Health Sciences Authority
Singapore

Dr Yasmin Ayob

National Blood Centre
Ministry of Health
Malaysia

Dr Zarin Bharucha

Indian Red Cross Society
Bombay City Branch Blood Centre
India

Dr Xu Zhong

Shanghai (Red Cross) Blood Centre
Shanghai
China

Dr Wai-Chiu Tsoi

Hong Kong Red Cross Blood Transfusion
Services
Hong Kong
China

Dr Soisaang Phikulsood

National Blood Centre
Thai Red Cross Society
Bangkok
Thailand

Arch. Rebecca Penafiel

National Centre for Health Facility
Development
Department of Health
Manila
Philippines

Dr. Neelam Dhingra

Blood Transfusion Safety
World Health Organization,
Headquarters
Geneva,
Switzerland

Mr. Yu Junping

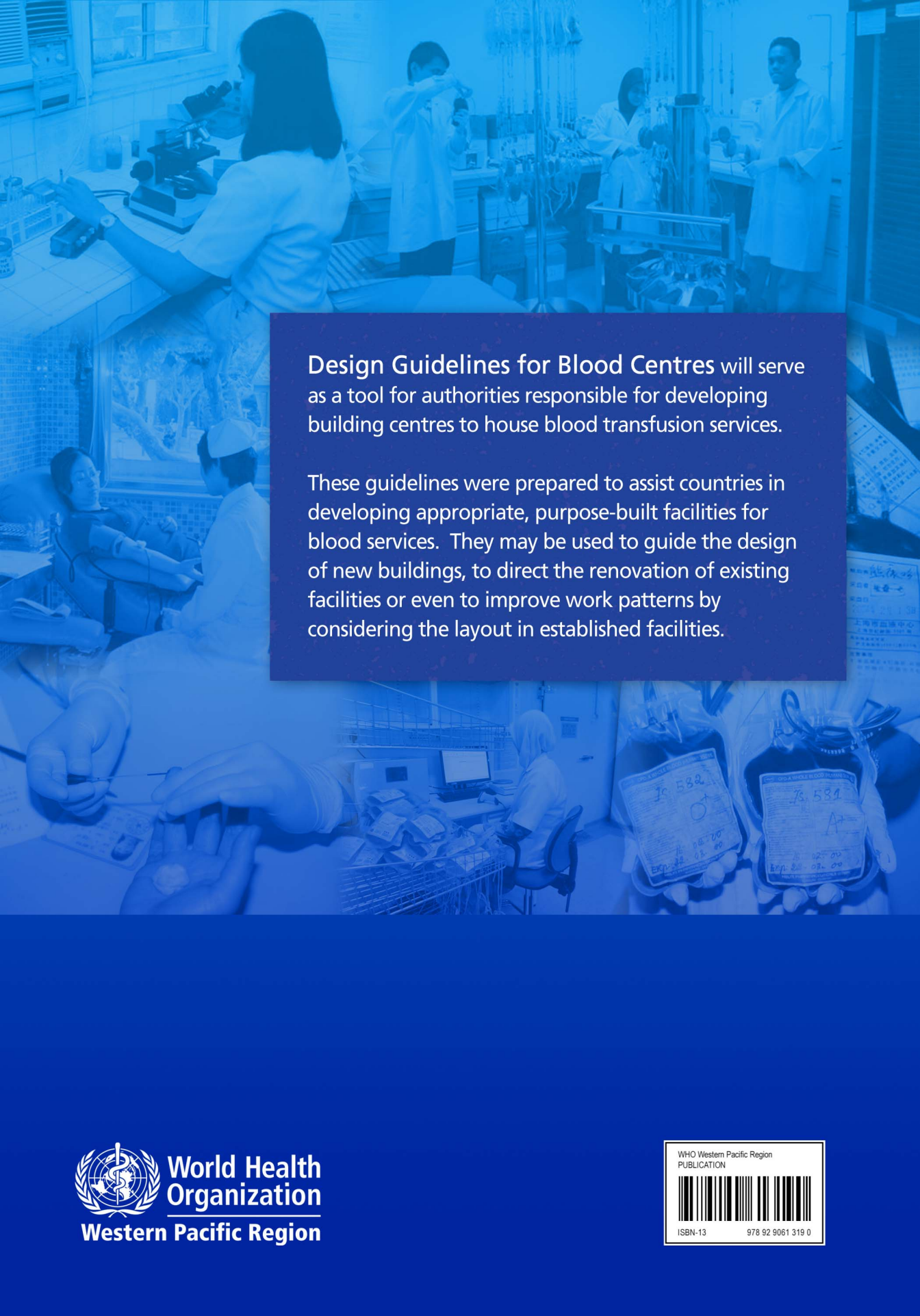
Blood Transfusion Safety
World Health Organization,
Headquarters
Geneva,
Switzerland

Dr. Rajesh Bhatia

Blood Safety & Laboratory Technology
World Health Organization
South East Asia Regional Office
New Delhi,
India

Dr Gayatri Ghadiok

Health Technologies and Laboratory
World Health Organization
Western Pacific Regional Office
Manila,
Philippines



Design Guidelines for Blood Centres will serve as a tool for authorities responsible for developing building centres to house blood transfusion services.

These guidelines were prepared to assist countries in developing appropriate, purpose-built facilities for blood services. They may be used to guide the design of new buildings, to direct the renovation of existing facilities or even to improve work patterns by considering the layout in established facilities.

